CUBEscan

BioCon-500™

User Guide

Man, Machine & Medicine
Mcube Technology Co., Ltd.

CUBESCAN BioCon-500™

Bladder Volume Measurement System

User Guide

CAUTION: Federal Law restricts this device to sale by or on the order of a physician.

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1 DEFINITIONS

These definitions are used in this user guide.

WARNING: Describes precautions necessary to prevent injury or loss of life.

CAUTION: Describes precautions necessary to protect the products.

IMPORTANT: Describes information that a user should know for safe and effective use of this system.

SCAN : Tactile switch

***SCAN* :** Context menu based on system state (Screen)

2 GENERAL INFORMATION

2.1 Indications for Use

The **BioCon-500™** is a B-mode pulsed-echo ultrasound device. The **BioCon-500™** is intended as a portable battery-operated device. The **BioCon-500™** projects ultrasonic energy through the abdomen of the patient obtaining images of the bladder in order to calculate the urine volume non-invasively. The **BioCon-500™** is intended to be used only by qualified medical professionals. Contraindications for the **BioCon-500™** are fetal use and use on pregnant patients.

2.2 Contraindications

Do not use the **BioCon-500™** on following cases:

a) Fetal use or pregnant patients.
b) Patients with ascites.
c) Patients with open or damaged skin.
d) Wounds in the suprapubic region.

2.3 Prescription Statement

Caution: Federal Law restricts this device to sale by or on the order of a physician.

2.4 Safety

This guide covers components, function, maintenance, storage, and precautions needed to use this system. All users must read and thoroughly understand this entire guide prior to using the **BioCon-500™**. This section has information on safe use of the **BioCon-500™** (Electrical Safety, Battery Safety, EMC (Electromagnetic Compatibility), Equipment Safety).

WARNING:

- **Risk of explosion:**
  To avoid the risk of injury, do not operate the device in the presence of flammable gasses or anesthetics. The hazard of potential explosion exists.

2.4.1 Electrical Safety

This device meets IEC 60601-1, Class Ⅰ, Type BF isolated patient-applied parts safety requirements. This device complies with the applicable medical equipment requirements published in the Canadian Standards Association (CSA), European Harmonized Standards, and Underwriters Laboratories(UL) safety standards.

Please review and follow the following safety warnings.

WARNING:

- The power supply should be properly grounded. The power supply must be connected to an AC socket that is medical grade or equivalent. The grounding pin must not be removed or tampered with.
- Do not use the device if the power cord is damaged.
- Do not open the device's enclosures. All servicing, except battery and printer paper replacement, must be made by a qualified technician.
- Inspect the transducer and cable prior to using the device. Do not use if the transducer or cable is damaged.
- Use the device within operating conditions specified in chapter 10 "Environmental conditions."
- Do not use the device with any defibrillator at the same time.
- Use accessories only recommended by Mcube Technology.
- Do not use if the transducer that has been immersed beyond the specified cleaning or disinfection level.

WARNING:

- The device should be used with ultrasonic gel either applied on the probe or patient's abdomen. Thus, users should avoid using this device on patients with skin disease or injury.
- **Power Cord:**
  Make sure the power cord is the correct type for your area. The equipment has a universal power adapter that allows operation at either 100-120V AC or at 200-240V AC without the need for user adjustment.
  Always use a hospital grade power cord with the correct plug type. The cord must be rated for 125VAC at 15A, and be of type SJT or better.
- **Adapter:**
  The device complies to the above standards only when used with the power cord included.. Only use adapters supplied by Mcube Technology. (see chapter 9.4 Specification of adapter).
- **Computer connection:**
  When connecting the **BioCon-500™** to a computer, the computer must be certified to EN/IEC/CSA/UL 60950 or 60101-1 standard to maintain the device's compliance to EN/IEC/CSA/UL 60601-1-1 standard.
- **Transmission of data:**
  When transmitting data to or from a computer, make sure that the **BioCon-500™**, any accessories, and the computer are at least 2 meters or 6.5 feet away from the patient.

2.4.2 Battery Safety

BioCon-500™ uses a Lithium-ion battery pack. To ensure safe use of the battery, observe the following warnings and cautions. If there are any problems with the battery module, immediately discontinue use of the battery and contact Mcube Technology or your local distributor.

WARNING:

- The battery module has built in safety mechanisms. Do not disassemble or tamper with the battery pack.
- Only use the charger that is supplied with the Unit. Contact Mcube Technology or your local distributor for replacements. Do not charge the battery outside of the recommended conditions, as it may damage the battery resulting in possible leakage of the electrolyte or explosion (see chapter 9.4 Specification of adapter). Charge the batteries only when the ambient temperature is between +10℃ and +40℃ (+50 - +104°F)(in door use).
- Do not short-circuit the battery. Short circuiting the battery may cause rapid heating resulting is possible explosion. To avoid short-circuiting, do not let the battery come in contact with metal objects at any time, especially when transporting.
- Only use the manufacturer's recommended battery.
- Do not connect the battery in reverse polarity. Do not charge the battery in reverse polarity as it may cause the battery to rapidly heat, swell or even explode.
- Do not use a battery pack when something appears abnormal. Such as unusual smell, deformation, discoloration, etc.
- If electrolyte leakage occurs, do not touch the liquid. If it should come into contact with the skin or eyes, immediately seek help from a doctor.
- If the battery does vent, avoid any contact with the smoke.
- Do not expose the battery to water, moisture, or any type of liquid.
- Do not use or store the battery in temperatures above 60℃

	or next to any heat source. Doing so can cause the
WARNING:	battery pack to swell, and explode.
	● Do not abuse the battery pack. Doing so can cause damage to the battery resulting in a potentially unsafe situation.
CAUTION:	● When connecting the battery module to a console, be careful about polarity. Be sure to securely fasten the battery cover.
	● **Long term storage:** If the system is not likely to be used for more than a week, remove the battery module from the device and store it according to the recommended storage conditions. (See chapter 10 “Environmental conditions”)
IMPORTANT:	● To lengthen lifetime of the battery module, it is recommended to charge up to 75% and to discharge to 20%.
	● If the battery pack lasts less than 5 minutes after a full charging, replace the battery with a new one.

2.4.3 Electromagnetic compatibility

The **BioCon-500™** has been tested and found to comply with the electromagnetic compatibility (EMC) limits for medical devices as set forth in IEC 60601-1-2:2001. These limits are designed to provide reasonable protection against harmful interference in a typical medical installation.

CAUTION:

- To reduce the performance degradation of this device, use medical devices that comply with IEC 60601-1-2 EMC Standards in the vicinity.
- Do not use this device simultaneously with devices having high EMI levels.
- Electrostatic discharge (ESD) is a commonly occurring phenomenon especially when the humidity is low. Electrostatic discharge can cause damage to the transducer or the system. The following procedures can be useful in reducing the likelihood of ESD: anti-static spray on carpets, anti-static spray on linoleum, and anti-static mats.

2.4.3.1 Manufacturer's declaration - electromagnetic emissions

The BioCon-500 is intended for use in the electromagnetic environment specified below. The customer or the user of the BioCon-500 should assure that it is used in such an environment.		
Immunity test	Compliance	Electromagnetic environment -guidance
RF Emissions CISPR 11	Group 1	The BioCon-500 uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment
RF Emissions CISPR 11	Class A	The BioCon-500 is suitable for use in all establishments, other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes
Harmonic emissions	Class A	

IEC 61000-3-2		
Voltage fluctuations/ Flicker emissions IEC 61000-3-3	Complies	

2.4.3.2 Manufacturer's declaration - electromagnetic immunity

The BioCon-500 is intended for use in the electromagnetic environment specified below. The customer or the user of the BioCon-500 should assure that it is used in such an environment.			
Immunity test	IEC 60601 Test level	Compliance level	Electromagnetic environment
Electrostatic discharge (ESD) IEC 61000-4-2	±6kV Contact ±8kV air	±6kV Contact ±8kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2kV for power supply lines ± 1kV for input/output lines	±2kV for power supply lines ± 1kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1kV differential mode ±2kV common mode	±1kV differential mode ±2kV common mode	Mains power quality should be that of a typical commercial or hospital environment.

Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% UT (>95% dip in UT) for 0.5cycle 40% UT (60% dip in UT) for 5 cycle 70% UT (30% dip in UT) for 25 cycle <5% UT (<95% dip in UT) for 5 s	<5% UT (>95% dip in UT) for 0.5cycle 40% UT (60% dip in UT) for 5 cycle 70% UT (30% dip in UT) for 25 cycle <5% UT (<95% dip in UT) for 5 s	Mains power quality should be that of a typical commercial or hospital environment. If the user of the BioCon-500 requires continued operation during power mains interruptions, it is recommended that the BioCon-500 ultrasound system be powered from an uninterruptible power supply or a battery.
Power frequency (50/60Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE UT is the a.c. mains voltage prior to application of the test level.			

2.4.3.3 Manufacturer's declaration - electromagnetic immunity

The BioCon-500 is intended for use in the electromagnetic environment specified below. Users of the BioCon-500 should ensure that use occurs in such an environment

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80MHz	3 Vrms 150 kHz to 80MHz	Portable and mobile RF communications equipment should be used no closer to any part of the BioCon-500, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.

Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5GHz	3 V/m 80MHz to 2.5GHz	**Recommended separation distance** $d = [\frac{3,5}{V_1}]\sqrt{P}$ $d = [\frac{3,5}{E_1}]\sqrt{P}$ 80 MHz to 800 MHz $d = [\frac{7}{E_1}]\sqrt{P}$ 800 MHz to 2,5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, [a] should be less than the compliance level in each frequency range. [b] Interference may occur in the vicinity of equipment marked with the following symbol :

NOTE 1) At 80MHz and 800MHz, the higher frequency range applies.
NOTE 2) These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be

considered. If the measured field strength in the location in which the BioCon-500 is used exceeds the applicable RF compliance level above, the BioCon-500should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the BioCon-500.

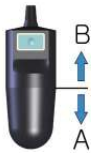
[b] Over the frequency range 150kHz to 80MHz, field strengths should be less than [V_1] V/m.

2.4.4 Equipment Safety

To prevent damage to the system and/or accessories, observe the following cautions.

CAUTION:

- A dirty transducer can degrade the accuracy of the system. Clean the transducer with a soft cloth dampened in a mild soap or detergent.
- Dropping a transducer or impact on a transducer can cause the system to malfunction or be inaccurate. Do not drop or shock the transducer.
- To avoid damaging the cable or transducer connector, handle them with care.
- Do not immerse the system or the transducer beyond the level in specified in 8.4 “Cleaning & Disinfection”
- If the system is not likely to be used for more than a week, charge the battery up to about a 75% charge level, remove the battery module from the device and store it according to storage conditions of the battery. This step will help maximize the lifetime of the battery. (See chapter 10 “Environmental conditions”)
- The device has a setting to power down automatically if not used during a specified time period. This setting may be adjusted by selecting the ‘Auto Power’ option in ‘Setup Menu’.
- The device will not power on without a battery installed.
- When measuring the urine volume of a patient, ensure that the probe’s **SCAN** button is on the right side of the patient.
- When using the system on a medical cart, ensure that the cart is placed on a flat and level surface.



- The safe level of immersion for the probe is marked by the border between the cap of the probe and the body of the probe. Do not immerse beyond the ‘B’ portion of the probe illustrated in the figure to the left.
- Only use the transducer which shipped with your unit
- The transducers are not interchangeable between units, They are calibrated to a specific machine. If changing the

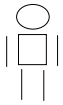
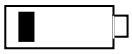
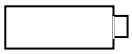
probe associated with a machine, it is necessary to calibrate the two prior to deployment

2.5 Safe Handling Procedures for Transporter

Quarantine: Packages that are crushed, punctured or torn open to reveal contents should not be placed into deployment. Such packages should be isolated until the shipper has been contacted, provides disposition instructions and, if appropriate, arranges to have the product inspected and repacked.

Spoiled Product: In the event that damage to packaging results in damage to the battery causing released electrolyte, the spill should be contained and the shipper should be contacted for instructions.

2.6 User Interface Icon Definitions

Symbol	Meaning
	Indicates a male patient
	Indicates a female patient
	Indicates a battery more than 75% charged
	Indicates a battery 50~75% charged
	Indicates a battery 25~50% charged
	Indicates a battery 5~25% charged
	Indicates the battery is near depletion or depleted

3 INTRODUCTION

3.1 Product Description

BioCon-500™ is a portable ultrasound system intended to measure the volume of urine in a patient's bladder. **BioCon-500™** transmits ultrasound signals into the abdomen of a patient and receives the echoed signals. Using the echoed signals, the system determines the bladder's outline and calculates the volume of the bladder based on the outline.

BioCon-500™ has a Pre-Scan function, which shows a live ultrasound image of a horizontal planar cross-section of the bladder found by using the echoed signals. The Pre-Scan function helps in locating the bladder and improving accuracy.

A user can print the results using a built-in thermal printer immediately after measurements are taken.

Also using the optional CubeScanPC software, one can upload saved data in a device's flash ROM to a computer for later review of the images.

Fig 1 BioCon-500™ System Front View

3.2 System Components

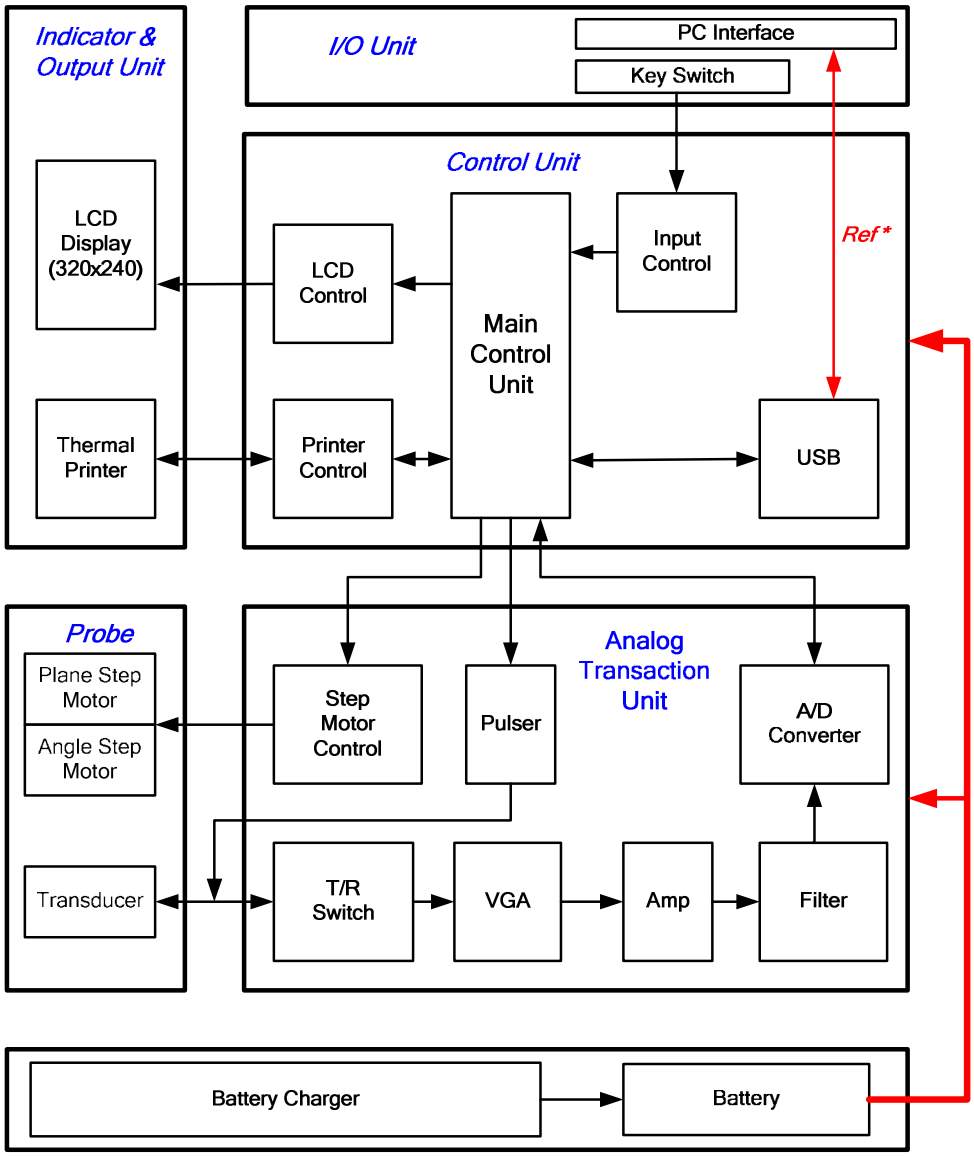
3.2.1 Packaging list

Part number	Parts	Description
3110100041	Console	
3110100037	Ultrasound probe	2.8MHz
4110100719	AC cord	Hospital grade NEMA 5-15
4110100069	Adapter(Power Supply)	Model: MW160KA1641F52
4110100744		Or Model: GTM21097-5012
4110100718	Thermal paper	Built in(57mm width) – 2 rolls
4110100714	Gel	Ultrasound transmission gel
5110100009	User guide	User guide

3.2.2 Optional components

Part number	Parts	Description
3110100032	Medical cart	Optional
5110100028	PC upload software CD	CubeScanPC setup CD (Optional)
4110100018	Battery Pack Module	Li18S
4110100070	USB cable	USB A-B cable(1.8M (Optional))

3.3 Functions of Each Part



*** Ref: This connection is used with optional CubeScanPC software.**

Fig 2 System Diagram (excluding power supply)

3.3.1 Console

Fig 3 Front of the console

No.	Item	Function	Remark
1	LCD	Displays menus and information.	
2	Thermal printer	Prints out the measured data.	
3	Indication lamp	**Green lamp(left)** : Adapter connection status On: Adapter connected. Off: Adapter disconnected* **Yellow lamp(right)** : Charging status On: Charging	
4	ENTER & arrow buttons	Depends on the system state.	
5	POWER button	Turns the system on / off	
6	PRINT button	Depends on the system state.	
7	SCAN button	Depends on the system state.	

* During pre-scan and/or scan operation, the yellow lamp will turn off regardless of the charging state.

Fig 4 Right-side view of the console

No.	Item	Function	Remark
1	USB terminal	Terminal for USB connection with a computer.	
2	Probe terminal	Connects a probe to a console.	

Fig 5 Left-side view of the console

No.	Item	Function	Remark
1	Adapter terminal	Terminal for adapter connection to a console.	

Fig 6 Rear view of the console

No.	Item	Function	Remark
1	Handle	Can be used to facilitate carrying	
2	Battery cover	Cover for the battery compartment	

3.3.2 Ultrasonic Probe

Fig 7 Ultrasonic probe and cable

No.	Item	Function	Remark
1	Probe cap	Transmits and receives ultrasound signals	
2	Cable	Connects the probe to console.	
3	Connector	Connects the ultrasonic cable to the console	
4	SCAN button	The same function as a SCAN button on the console.	

4 SETUP

4.1 Installing or Removing the Battery

The battery is installed in a bay in the **BioCon-500™**. When changing the battery or removing the battery for storage, follow these instructions.

Power off	1) Turn the system off.
Disconnect accessories	2) Disconnect all connections from the console.
	3) Loosen the two screws using a screwdriver.
	4) Remove the battery cover. **IMPORTANT:** When removing the battery cover, be careful to not bend the cover.
	5) Pull out the battery using the strap on the battery.
	6) Insert the new battery. When inserting, the top side of the battery (the side having LED) should be down (facing the bottom of the unit) and the strap on the battery should be be facing outwards. The battery cannot be properly installed if the orientation is incorrect.

WARNING: | ● To avoid the risk of explosion, only use batteries

recommended by Mcube Technology.

CAUTION:

- Never use excessive force to install the battery.

4.2 Changing the Thermal Paper

		1) Open the printer cover as shown to the left.
		2) Pull out the empty bobbin. 3) With the printer paper in one hand, unroll a small length of the paper and insert into the unit as shown.
		4) Close the printer cover after inserting the paper.

CAUTION:

- Be sure to insert the paper in the correct orientation.
- To avoid damaging the system:
  - Only use thermal paper recommended by Mcube Technology.
  - Only print when the thermal paper is correctly loaded.

4.3 Charging the Battery Module of the BioCon-500™

	1) Connect an AC cord to a DC adapter.
	2) The picture shows an adapter with the AC cord properly connected.
	3) Connect the DC jack to the adapter terminal of the console.
	4) The pricture shows a console with the proper connection to the DC jack.
	5) Connect the AC plug to a grounded socket.

	6) Check the color indicator on the console. *__Green indicator:__ Tells that the adapter connected and AC power is present. The system is ready to charge and be operated. *__Yellow indicator:__ Denotes that the system is charging. When the battery is fully charged, the yellow indicator goes off. *Fully charging the battery may take up to 10 hours..

WARNING:

- Only use AC Adapters recommended by Mcube Technology.
- To avoid electric shock, only use sockets with a ground pin.

4.4 Connecting the Probe to the System

	1. Find the white mark on the connector of the probe.
	2. Align the probe cable to the probe terminal with the white mark (①) on the probe connector up. After aligning, push the probe cable straight in until there is a click sound. * To disconnect the probe from the console, grasp the black plastic ring (2) on the probe connector and pull out.
	3. Check to make sure the connection is secure.

4.5 Rolling Cart Assembly

CUBEscan BioCon-500 Rolling Cart

Rolling Cart Part List

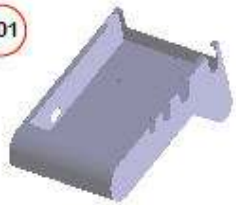
NUMBER	NAME	PART NUMBER	Quantity
P01	Main body holder	4110100153	1EA
P02	Adaper holder	4110100154	1EA
P03	Probe holder	4110100155	1EA
P04	Gel holder	4110100156	1EA
P05	Basket plate module	4110100167(Plate) 4110100169(Plate guide 1) 4110100170(Plate guide 2)	1EA 2EA 2EA
P06	Chart basket	4110100174	1EA
P07	Hub	4110100161	1EA
P08	Leg module	4110100165(Leg) 4110100166(Caster)	5EA 5EA
P09	Lower column	4110100157	1EA
P10	Upper column	4110100158	1EA
P11	Spring	4110100159	1EA
P12	Lock handle	4110100160	1EA
T01	3mm Hexagon wrench	TOOL	1EA
T02	5mm Hexagon wrench	TOOL	1EA
T03	10mm Hexagon wrench	TOOL	1EA
B01	M4 X 8mm	Bolt	13EA
B02	M4 X 10mm	Bolt	2EA
B03	M4 X 20mm	Bolt	1EA
B04	M6 X 25mm	Bolt	5EA
B05	M10 X 25mm	Bolt	1EA

BioCon-500 Rolling Cart

Title: Components in a cart package

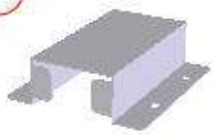
Part

P01



Main body Holder: 1EA
Part Number: 4110100153

P02



Adapter Holder: 1EA
Part Number: 4110100154

P03

Probe Holder: 1EA
Part Number: 4110100155

P04

Gel Holder: 1EA
Part Number: 4110100156

P05

Basket Plate Module: 1EA
Part Number: 4110100167
4110100169
4110100170

P06

Chart basket: 1EA
Part Number: 4110100174

P07

Hub: 1EA
Part Number: 4110100161

P08

Leg Module: 5EA
Part Number: 4110100165
4110100166

P09

Lower Column: 1EA
Part Number: 4110100157

P10

Upper Column: 1EA
Part Number: 4110100158

P11

Spring: 1EA
Part Number: 4110100159

P12

Lock Handle: 1EA
Part Number: 4110100160

Tool

T01

3mm Hexagon Wrench: 1EA

T02

5mm Hexagon Wrench: 1EA

T03

10mm Hexagon Wrench: 1EA

Bolt

B01

Hexagon Wrench Bolt
M4 X8mm: 13EA

B02

Hexagon Wrench Bolt
M4 X10mm: 2EA

B03

Hexagon Wrench Bolt
M4 X20mm: 1EA

B04

Hexagon Wrench Bolt
M6 X25mm: 5EA

B05

Hexagon Wrench Bolt
M10 X25mm: 1EA

BioCon-500 Rolling Cart

Title: Assembly order

1

Part A Assembly(Page 3)

2

Part B Assembly(Page 4)

3

Part C,D Assembly(Page 5, 6)

4

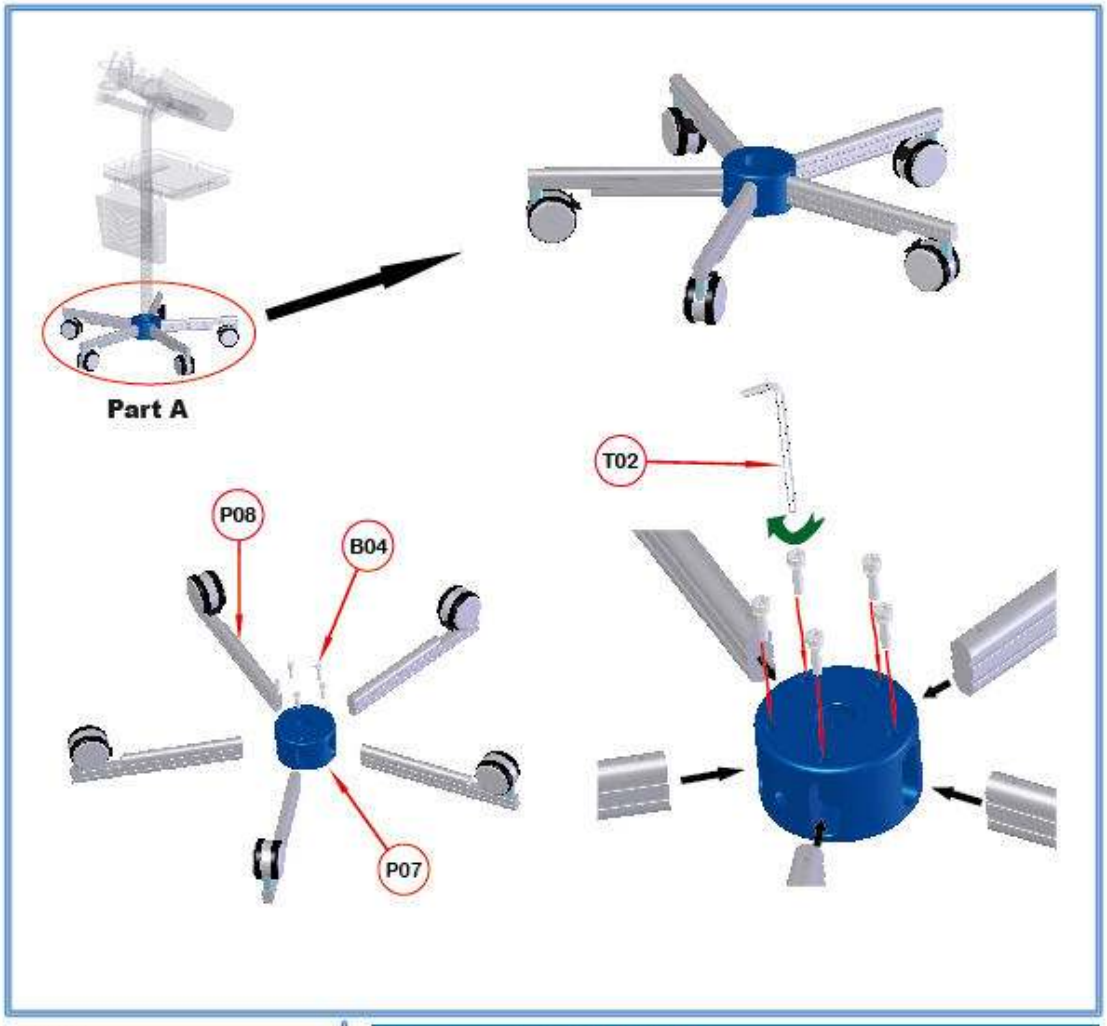
Part E Assembly(Page 7)

5

Part All Assembly(Page 8)

BioCon-500 Rolling Cart

Title: Part A - 5 Legs Assembly



ITEMS

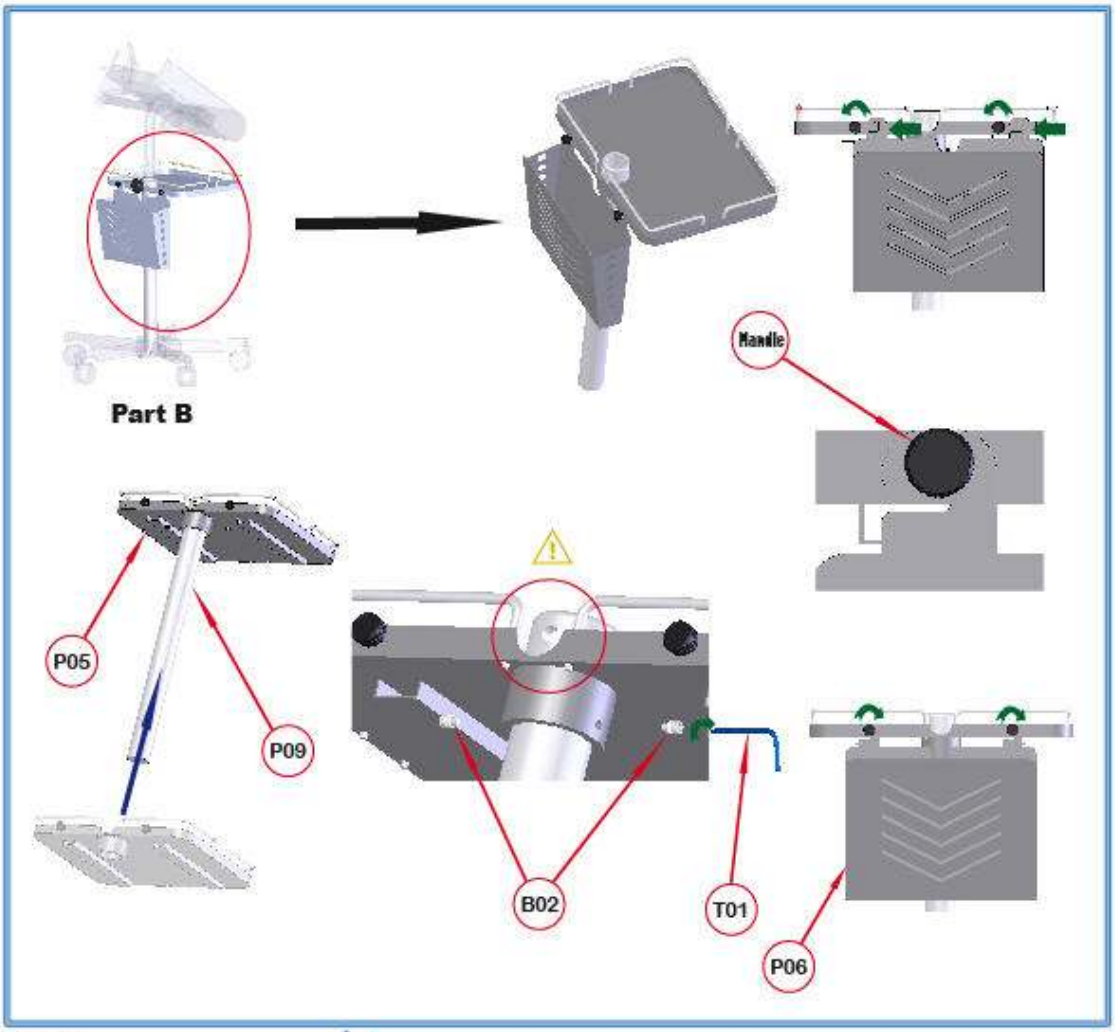
P07	: Hub	1EA
P08	: Leg	5EA
B04	: Wrench washer bolt (M6 X 25mm)	5EA
T02	: 5mm Hexagon Wrench	Tool

01. Part A ASSEMBLY

1. Put a leg with caster into the Hub, and then assemble the Hub by using wrench washer blot with a 5mm Hexagon wrench.
2. Assemble the rest 4 legs in the same way.

BioCon-500 Rolling Cart

Title: Part B - Basket Assembly



ITEMS

P05	: Basket plate	1EA
P06	: Chart basket	1EA
P09	: Lowercolumn	1EA
B02	: Wrench washer bolt	2EA
T01	(M4 X 10mm)	
	: 3mm Hexagon Wrench	Tool

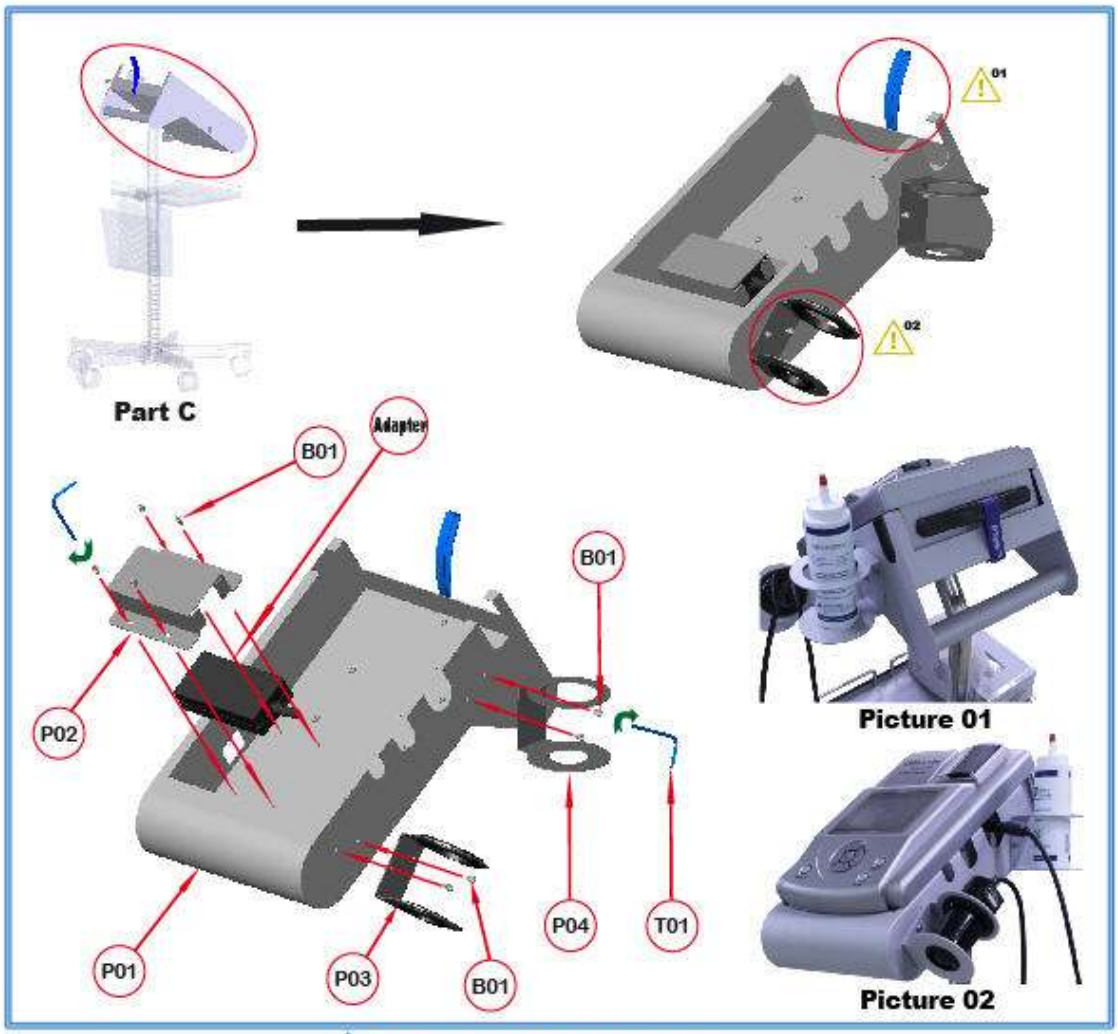
02. Part B ASSEMBLY

1. Put the Basket plate to Lower column from bottom-side to top-side as shown in the picture.
2. Settle the Basket plate to Lower column by using Wrench washer blot.
3. Unfasten the handle of Plate and fix into the hook of basket's upper side. And then fasten the handle of Plate.
   If you don't need basket, keep it separately.

⚠ Tap hole of the Lower column and circle of Basket plate should be aligned.

BioCon-500 Rolling Cart

Title: Part C - Shelf holdr Assembly



ITEMS

P01	: Main body holder	1EA
P02	: Adapter holder	1EA
P03	: Probe holder	1EA
P04	: Gel holder	1EA
B01	Wrench washer bolt (M4 X 8mm)	8EA
T01	: 3mm Hexagon Wrench	Tool

03. Part C ASSEMBLY

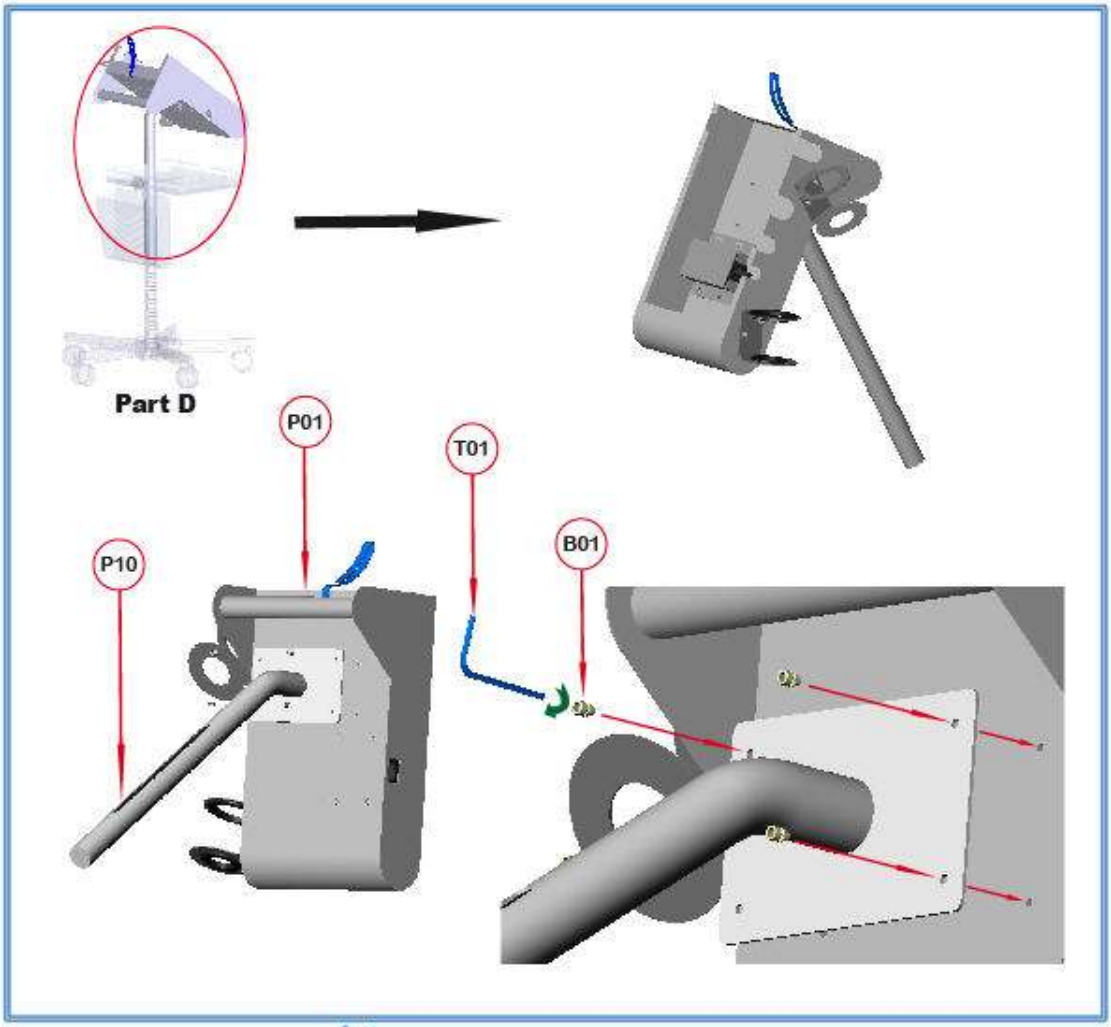
1. Fix the Adapter with Adapter holder the Main Body Holder.
   (When you are doing this operation, you can only use the adapter which was provided with the BioCon-500.)
2. Assemble the Probe holder and Gel holder.
   (Don't assemble reversely or changed.)

01 After fitting the main body of the BioCon-500 tie up the handle of BioCon-500 with Trolley set by using strap. [Picture 01]

02 Place the Probe and Gel properly as like picture. [Picture 02]

BioCon-500 Rolling Cart

Title: Part D - Upper column Assembly



ITEMS

P01	: Main Body holder (Assembly)	1EA
P10	: Upper column	1EA
B01	: Wrench washer bolt (M4 X 8mm)	4EA
T01	: 3mm Hexagon Wrench	Tool

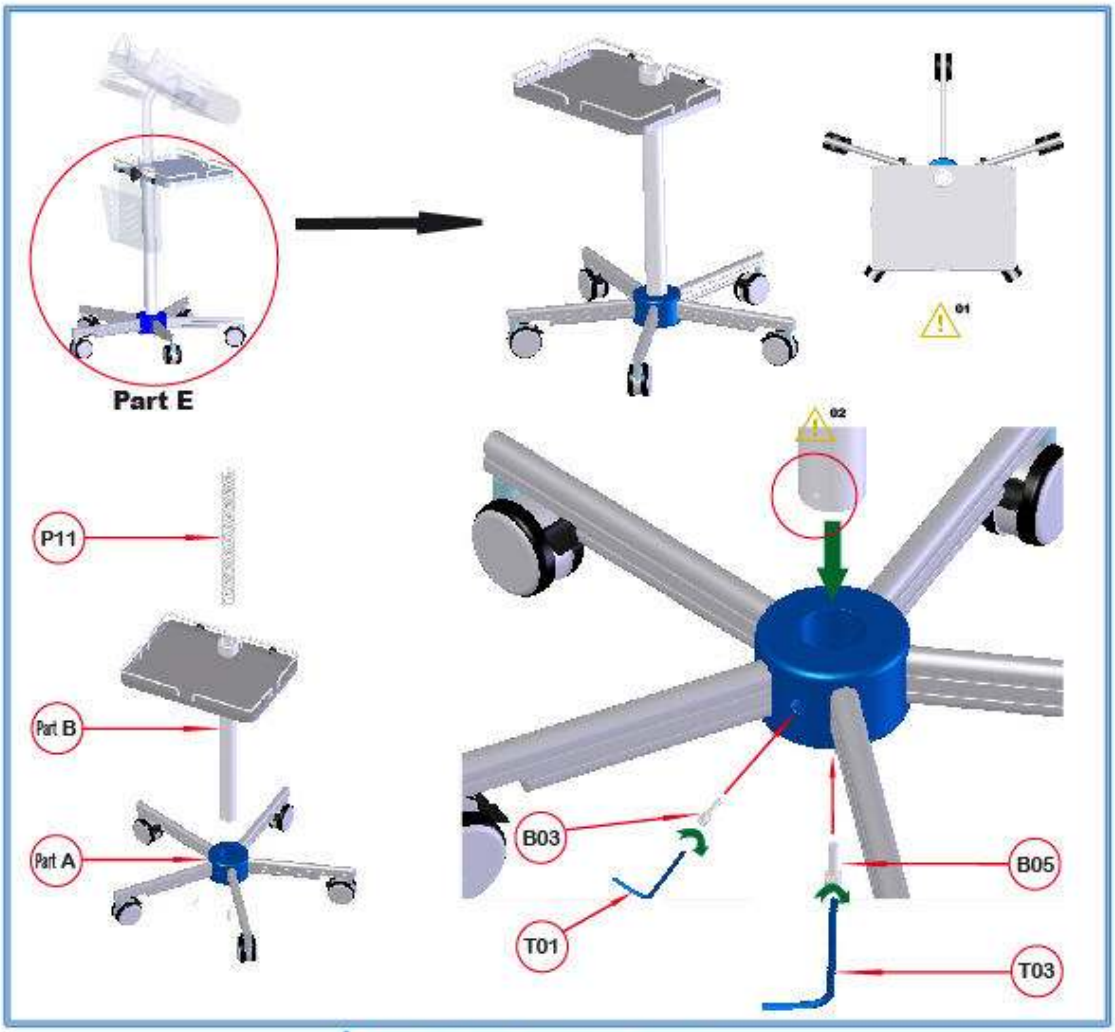
04. Part D ASSEMBLY

1. Assemble the Upper column to the Main Body holder (Assembly) as a proper direction like picture.
(When you are doing this operation, you should be careful about the assemble direction.)

⚠ Caution: After assembling if you lay down to right side, Holders can be bent.

BioCon-500 Rolling Cart

Title: Part E - Bottom Assembly



ITEMS

PartA	: 5 Leg Assembly	1EA
PartB	: Basket Assembly	1EA
P11	: Spring	1EA
B03	: Wrench washer bolt (M4 X 20mm)	1EA
B05	: Wrench washer bolt (M6 X 25mm)	1EA
T01	: 3mm Hexagon Wrench	Tool
T03	: 5mm Hexagon Wrench	Tool

05. Part E ASSEMBLY

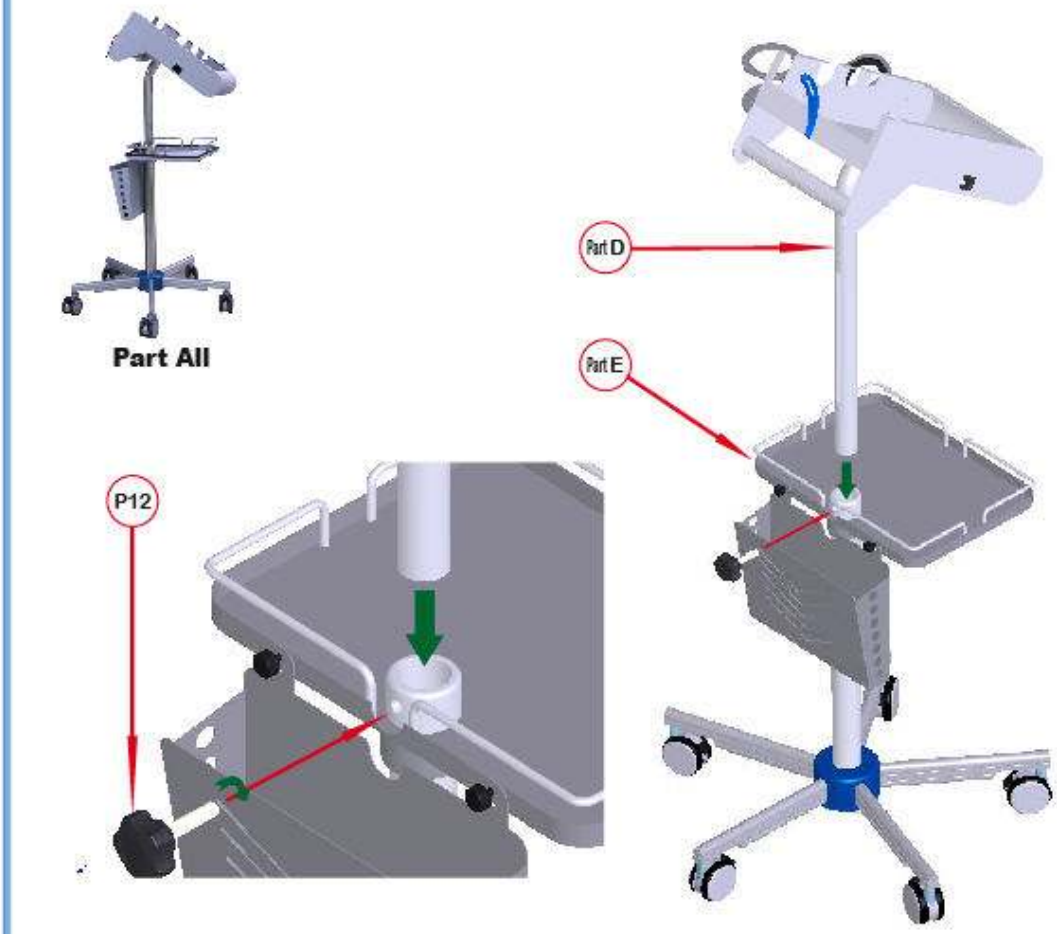
1. Put the part B assembly to Part A assembly in the proper direction, then fix the part B assembly by using B03 & B05 bolts.
2. Put the spring into the hole of part B's upside.

01 Check the direction after Part B assembling.

02 When you are inserting the Part B, hole and bar should be putted properly.

BioCon-500 Rolling Cart

Title: Part All - Assembly



ITEMS

PartD	: Upper column Assembly	1EA
PartE	: Bottom Assembly	1EA
P12	: Lock handle	1EA

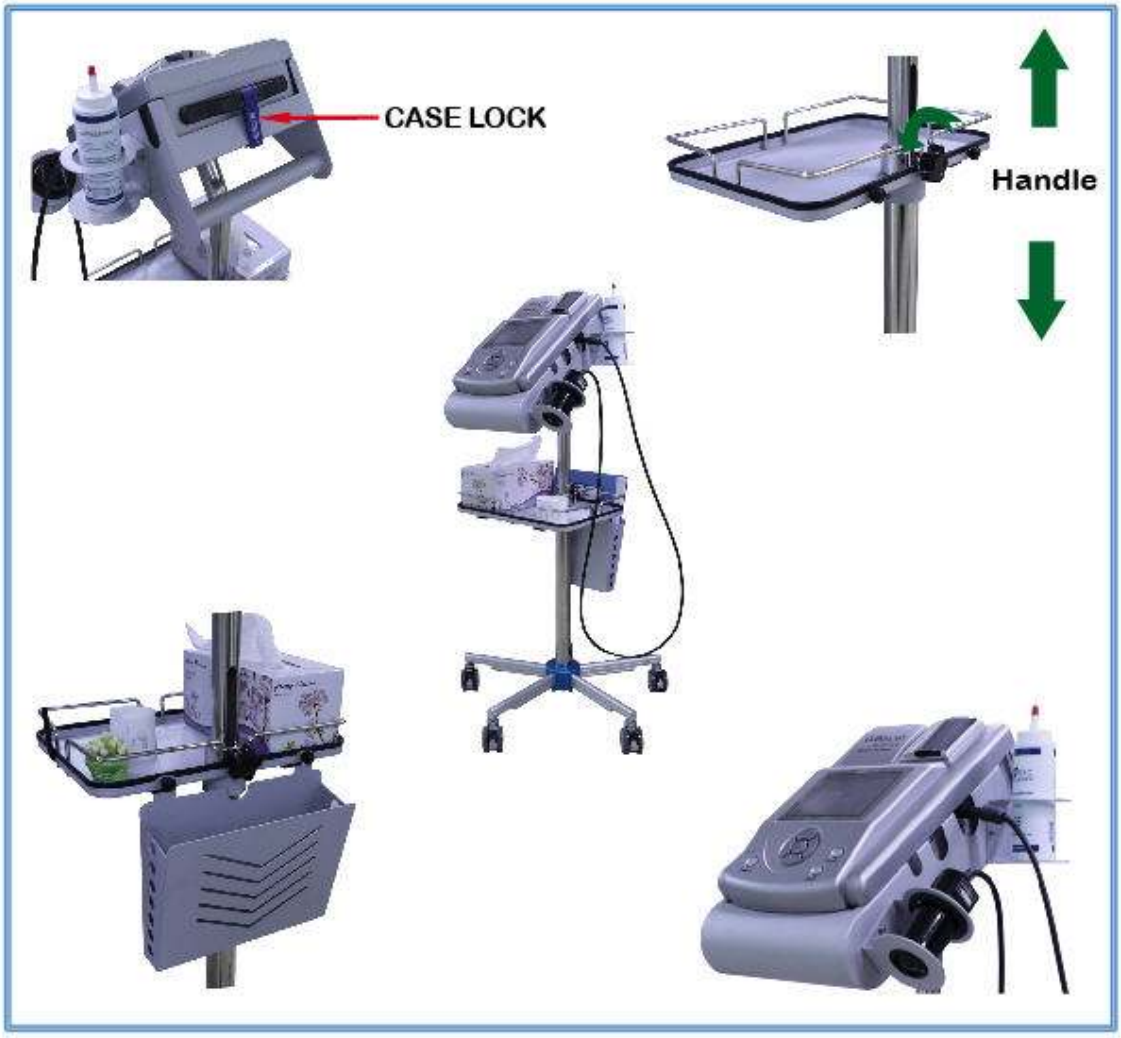
06. Part All ASSEMBLY

1. Put the Upper column Assembly to Bottom Assembly hole properly.
2. Lock up using the lock handle.

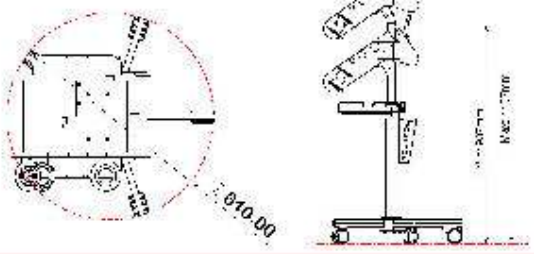
⚠ If you assemble the Lock handle first, Upper column Assembly might not be inserted.

BioCon-500 Rolling Cart

Title: How to use the rolling Cart



Dimensions : Ø610 X 1167mm(Max)
Weight : 11.5kg



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5 HOW TO USE

5.1 Quick Guide

BioCon500™ User quick Reference

1 **Turn On The System**

Press Power Button More Than 1 Second

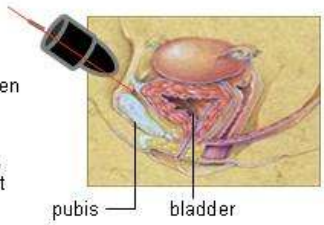
2 **Select Patient Type.**

3 **Apply Ultrasound Gel.**

4 **Aim Toward Bladder.**

Put the ultrasound probe on gel applied on the patient's abdomen and aim to bladder location expected.

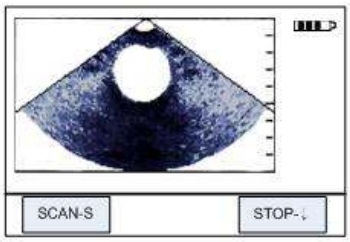
Important: When you put the probe on the patient's abdoment, be sure to that the SCAN switch of the probe places on the right side of the patient.



5 **Locate the bladder by Pre-Scan function.**

Press SCAN switch to start Pre-Scan, then a user can see the Pre-Scan Screen.

Important: The Pre-Scan is executed only when 'Prescan Enable' in setup menu is 'ON'.

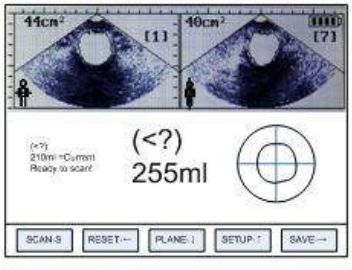


<Real Time Ultrasound Image>

6 **Scan Result Screen.**

The position the bladder image is the biggest will be the right position to start normal scan.
After locating the bladder position, press SCAN switch to start normal scan..
Verify the scan results and retry if needed

Important: When 'Prescan Enable' is off, normal scan will be executed if a user press SCAN switch on Top Screen.



<Scan Results Screen>

7 **Save and / or Print.**

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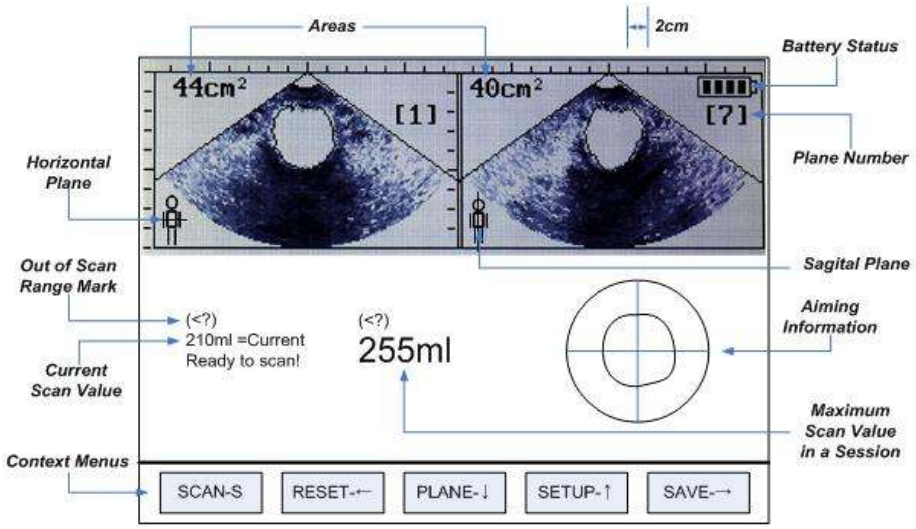
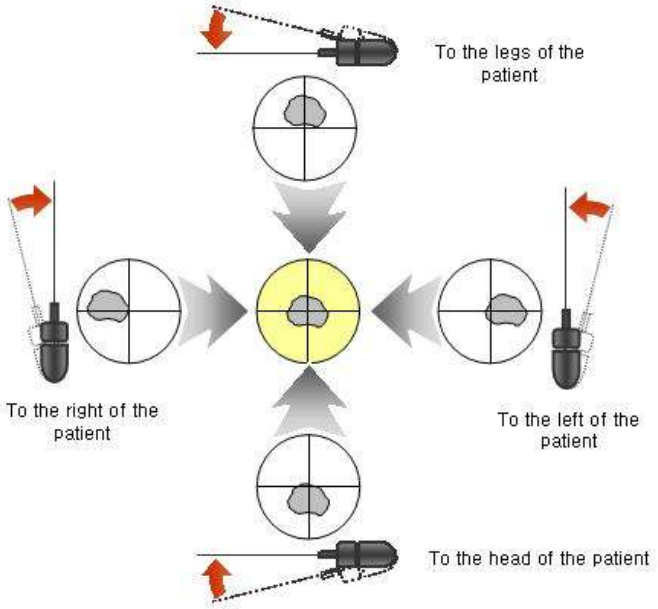
BioCon500™ User quick Reference



<Scan Results Screen>



<Diagram For Re-aiming>

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5.2 Device Controls and Contextual Menus

BioCon-500™ has 8 buttons on the main console. Only one of the buttons (POWER) has fixed functionality. It is used for turning the system on or off. The other 7 buttons navigate the contextual menus and have varying function. Contextual Menus in the bottom part of the display consist of an option and a corresponding button. For example, "SCAN-S," means that the option is ***SCAN***, and a tactile switch is SCAN. Table below explains the context menus and system state.

Switch State	SCAN	PRINT	LEFT	RIGHT	UP	DOWN	ENTER
Top Screen	*SCAN* *PSCAN*	-	*SEX*	*LOAD*	*SETUP*	*P_ID*	-
Setup Screen	-	*EXIT*	-	-	*MUP*	*MDOWN*	*SELCT*
Scan Results Screen	*SCAN* *PSCAN*	*PRINT**	*RESET*	*SAVE*	*SETUP*	*PLANE*	-
Pre-Scan Screen	*SCAN*	-	-	-	-	*STOP*	-
Load Screen	-	*PRINT*	*ERASE*	*TOP*	*NEXT*	*PLANE*	-
Erase Confirm Screen	-	*CFIRM*	*CANCEL*	-	-	-	-
Clinic Name Input Screen	*RCURS*	*EXIT*	*MLEFT**	*MRIT**	*MUP**	*MDOWN**	*INPUT*
Patient ID Input Screen	-	*EXIT*	*LCURS*	*RCURS*	*NUP*	*NDOWN*	-
Setup Data/Time	-	-	*LCURS*	*RCURS*	*NUP*	*NDOWN*	*ENTER*
Setup Other Option	-	-	*OUP*	*ODOWN*	-	-	*ENTER*

Screen							
Upload Screen	-	-	-	-	-	-	-

- Context menus marked * are not displayed in bottom of the display.

5.2.1 Functions in each context menu

Number	Context Menu	Function
1	*SCAN*	Initiate a bladder volume scan.
2	*PSCAN*	Pre-Scan for positioning the bladder.
3	*SEX*	Toggle between male and female.
4	*LOAD*	Load the saved data.
5	*SETUP*	Go to setup menu.
6	*P_ID*	Go to patient ID input screen.
7	*EXIT*	Go to previous system state.
8	*MUP*	Move the position cursor upward (circular).
9	*MDOWN*	Move the position cursor downward (circular).
10	*SELCT*	Select the item selected by position cursor.
11	*PRINT*	Print scan results or loaded data according to system state.
12	*RESET*	Clear the data in a current session and go to Top Screen.
13	*SAVE*	Save the data of current session to flash ROM.
14	*PLANE*	Show next two planes images and related numeric data.
15	*STOP*	Stop pre-scanning and go to previous system state.
16	*ERASE*	Go to Erase Confirm Screen for erasing current loaded data.
17	*CFIRM*	Erase current loaded data from flash ROM.
18	*CANCEL*	Go to Load Screen without erasing current loaded data.
19	*MLEFT*	Move the position cursor in Screen Keyboard to the left.
20	*MRIT*	Move the position cursor in Screen Keyboard to the right
21	*MUP*	Move the position cursor in Screen Keyboard to upwards
22	*MDOWN*	Move the position cursor in Screen Keyboard to downwards
23	*LCURS*	Move the cursor to left.

24	*RCURS*	Move the cursor to right.
25	*NUP*	Increase the value in current cursor (curcular).
26	*NDOWN*	Decrease the value in current cursor (curcular).
27	*INPUT*	Input the current character of the Screen Keyboard under the position cursor except in case of bottom line of the Screen Keyboard.
28	*ENTER*	Change the selected Setup Item option to the option on the display and save the Setup Item option to the flash ROM. And go to Setup Menu.
29	*OUP*	Show the next option upward for the current Setup Item.
30	*ODOWN*	Show the next option downward for the current Setup Item.

5.2.2 Combined Switches

Number	Combined Switches	Function	Active states
1	ENTER + UP	Brightness Up	Top Screen Scan Results Screen Load Screen
2	ENTER + DOWN	Brightness Down	
3	ENTER + LEFT	Change Image Contrast	Scan Results Screen Load Screen

5.3 Measuring Urine Volume

1) Charge Battery.

Charge the battery by connecting the AC Adapter to the AC main and to the console.

2) Turn on the system

Turn the system on by pressing and holding POWER switch for more than 1 second.

Then you can see the Top Screen as follows.

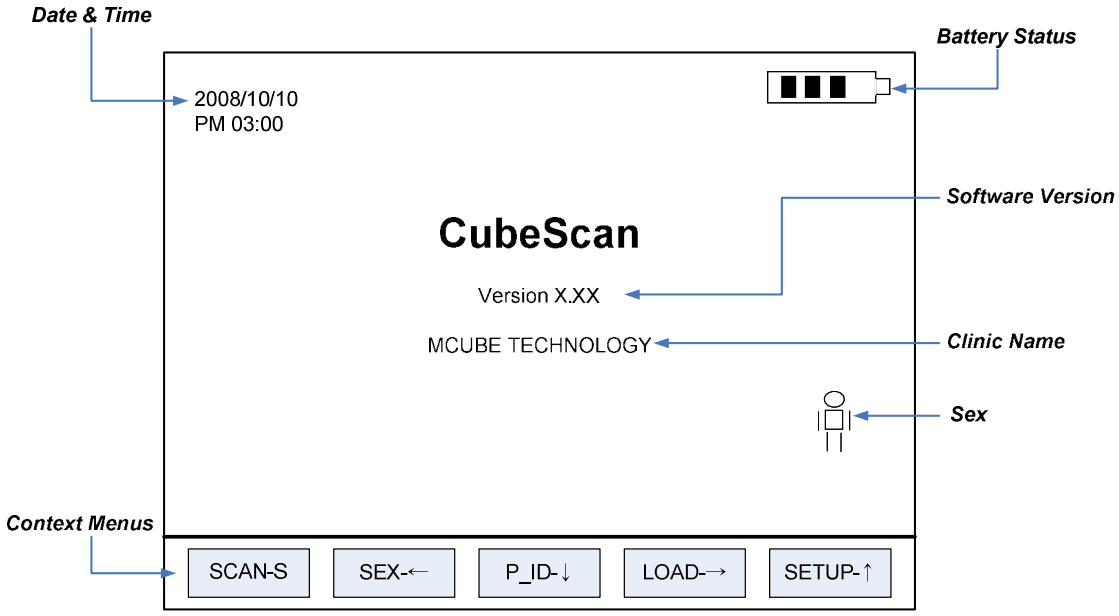
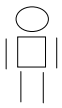


Fig 8 Top Screen

3) Select patient type.

Select patient type by pressing LEFT switch (*SEX* option) on Top Screen.

Each time a user presses the LEFT switch, the patient type mark will be changed.

 : A male patient

: A female patient

4) Apply the ultrasound gel

Apply the ultrasound gel on the patient's abdomen, above about 3~4cm above pubic symphysis.

5) Aim toward bladder

Put the ultrasound probe on gel applied to the patient's abdomen and aim at the location the bladder is expected to be in.

IMPORTANT:

- When you put the probe on the patient's abdomen, be sure that the SCAN switch of the probe places on the right side of the patient.

IMPORTANT:

- **Conditions to degrade the accuracy of the measurement:**
  - When a patient has had supra-pubic or pelvic surgery
  - A patient with catheter in his or her bladder
  - A patient with scar, sutures, staples or incisions in his or her abdomen
  - Air-gap between probe head and the skin of the patient
  - Use of the probe with unclean probe head
- **Use care when scanning in above conditions.**

6) Locate the bladder with the Pre-Scanning function.

Press SCAN switch to start Pre-Scanning and start displaying the prescan image on the main display. The position where the bladder image is largest and most centered is the optimal place to start the scan process.

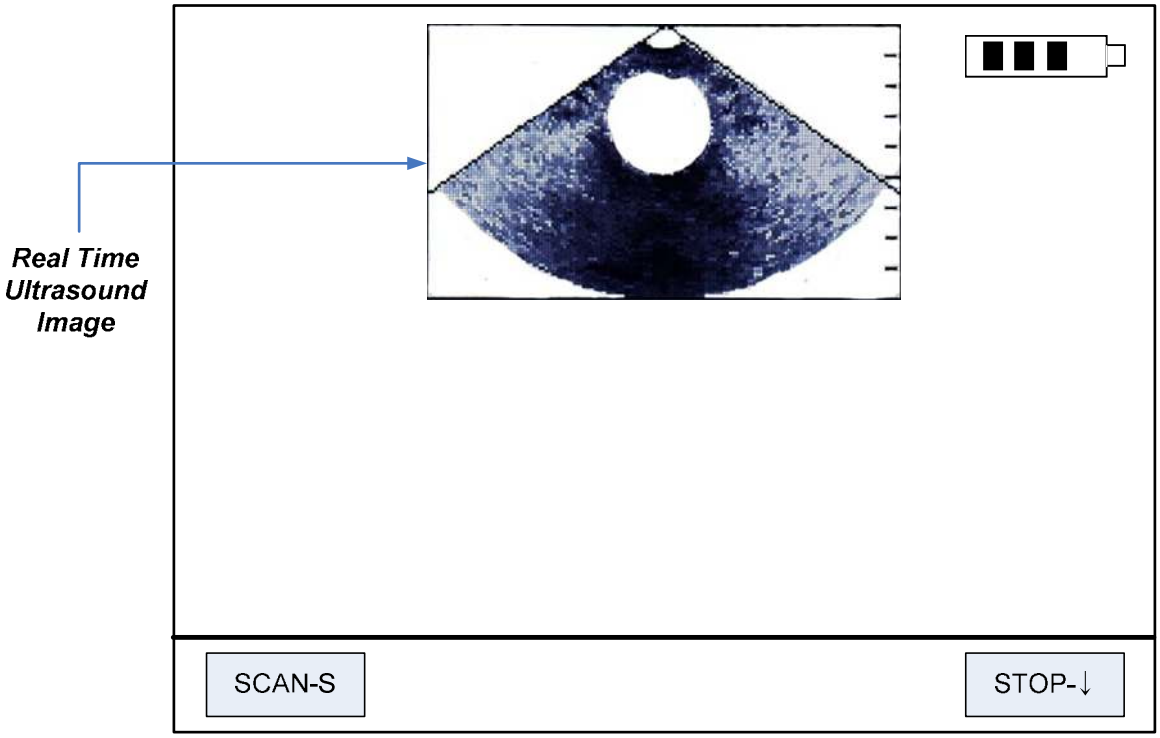


Fig 9 Pre-Scan Screen

IMPORTANT:

- The Pre-Scan is executed only when 'Prescan Enable' in setup menu is 'ON'. When 'Prescan Enable' is off, a normal scan will be executed the SCAN button is pressed on Top Screen.

7) After locating the optimal scanning location, press the SCAN button to start the bladder scan. The screen during normal bladder scanning is as follows.

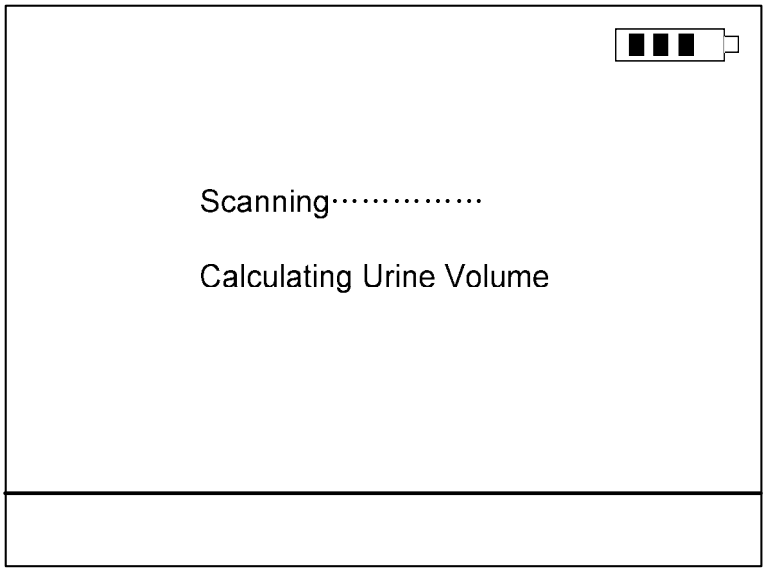


Fig 10 During-Scan Screen

8) Verify the scan results and rescan if needed.

After a normal scan, results will be displayed on the main display as follows.

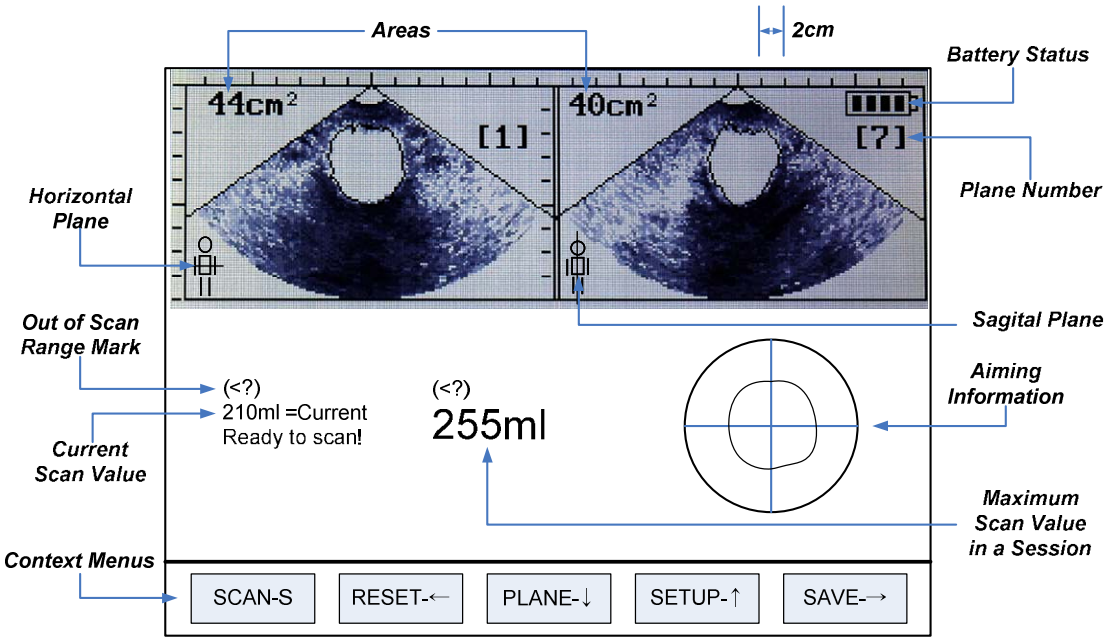


Fig 11 Scan Results Screen

In the aiming information in the Scan Results Screen, if the crossing of the aiming lines is not well centered on the bladder contour, you must re-aim and scan again. Also verify the bladder image and the detected bladder contour are in line with each other. If needed, re-aim and scan again.

How to re-aim

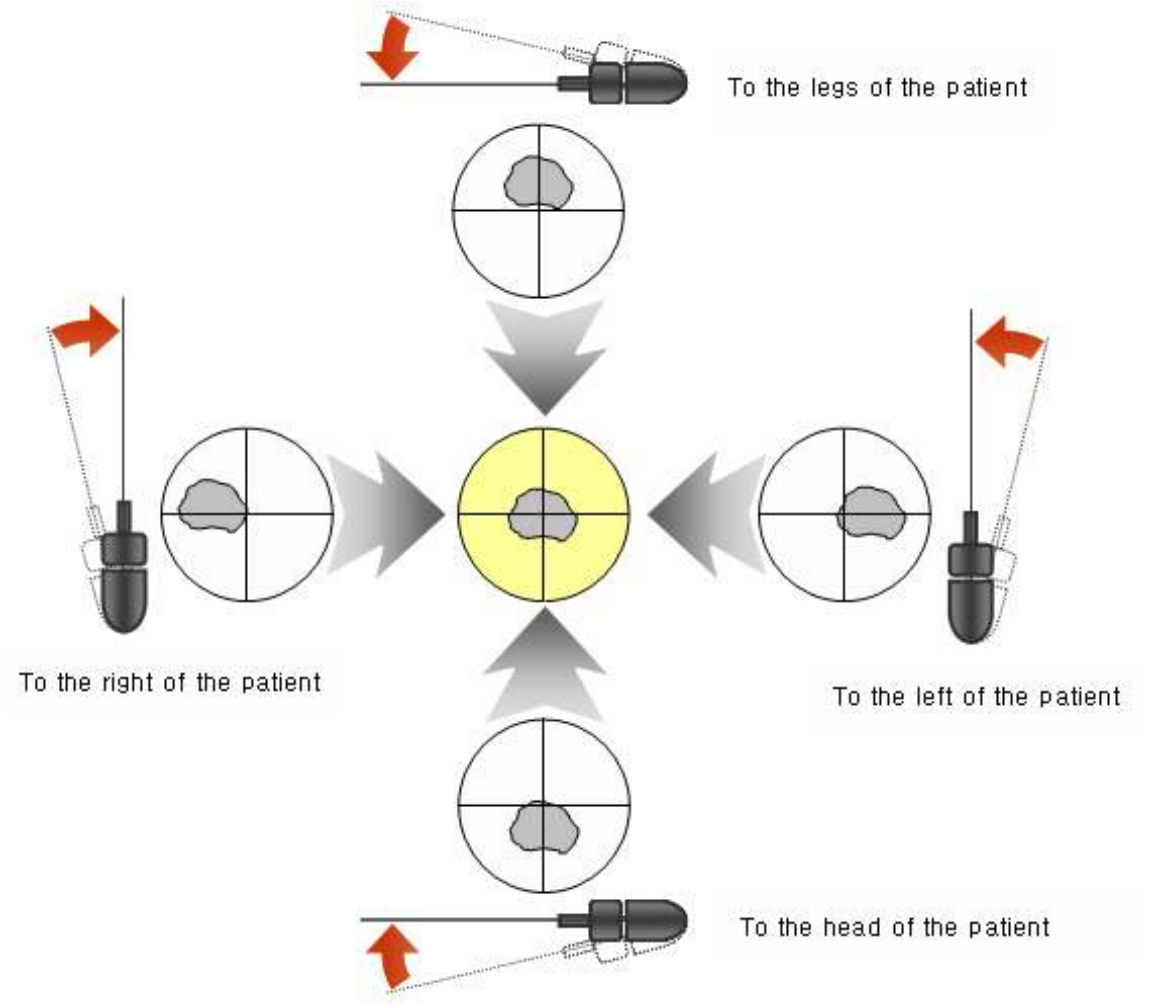


Fig 12 Diagram for re-aiming

9) Review, save and print scan results

To review other planes press DOWN (*PLANE* option) on the Scan Results Screen. To save the scan results press RIGHT (*SAVE* option) on the Scan Results Screen. To print the scan results press PRINT on the Scan Results Screen. *PLANE* option is not displayed on the context menus in bottom part of LCD**.**

IMPORTANT:

- During one session a user may scan more than 1 time. In this case the scan results with the largest urine volume will be saved and printed.
- In case there are multiple scans with the same urine volume, the most recent will be saved and printed.
- If a user saves twice in same session, the data that was previously saved will be overwritten. Only one data set will be saved per each session.
- **BioCon-500™** can save up to 5 scans.
- If a user saves more than 5 scans, the oldest scan will be overwritten with the newest scan data..

10) Finish scan.

After finishing the scan, wipe the ultrasound gel off the patient and the probe.

5.4 Changing the Patient ID

1) Press DOWN (*P_ID* menu) on the Top Screen.

Then a user can see the Patient ID Input Screen as follows.

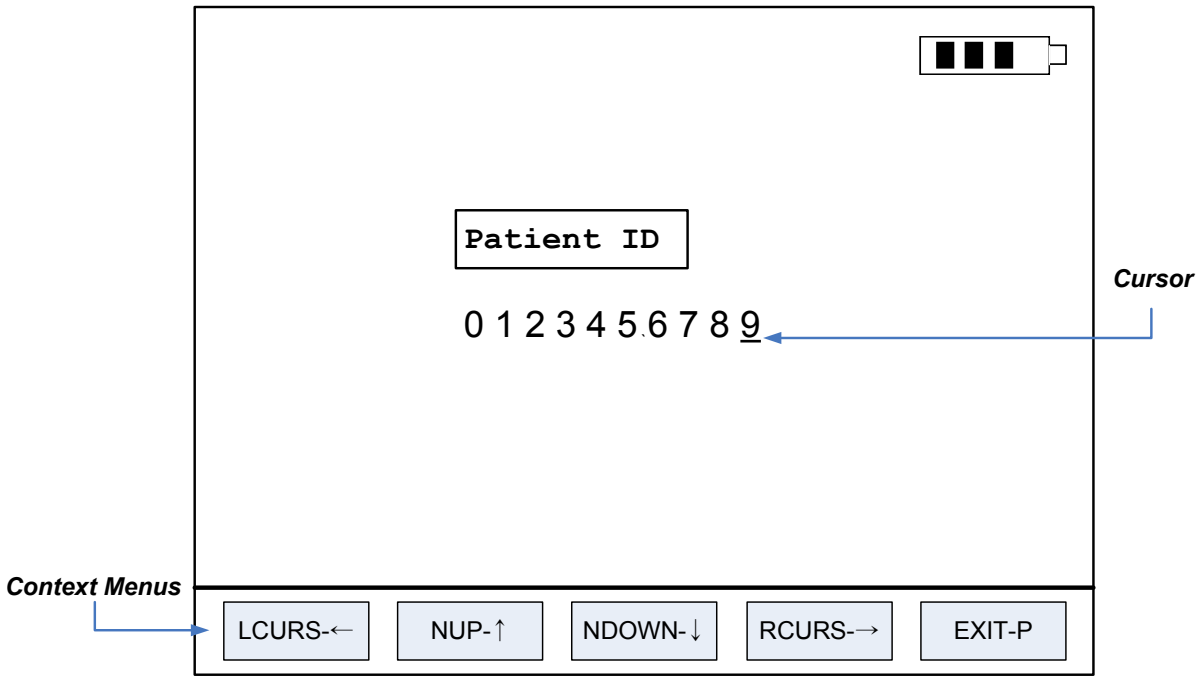


Fig 13 Patient ID Input Screen

2) Change the Patient ID.

To move the cursor, press LEFT (*LCURS* option) or RIGHT (*RCURS* option).
To change the value at the selection point, press UP (*NUP* option) or DOWN (*NDOWN* option)

IMPORTANT:

- The patient ID consists of 10 digits.
- The patient ID is not saved in flash ROM, so after restarting the system the patient ID will be reset to '0000000000'.

3) Go to Top screen by pressing PRINT (*EXIT* option) after editing the patient ID.

5.5 Loading the Saved Data

Press RIGHT (*P_ID* menu) on the Top Screen.

The Load Screen will be as follows.

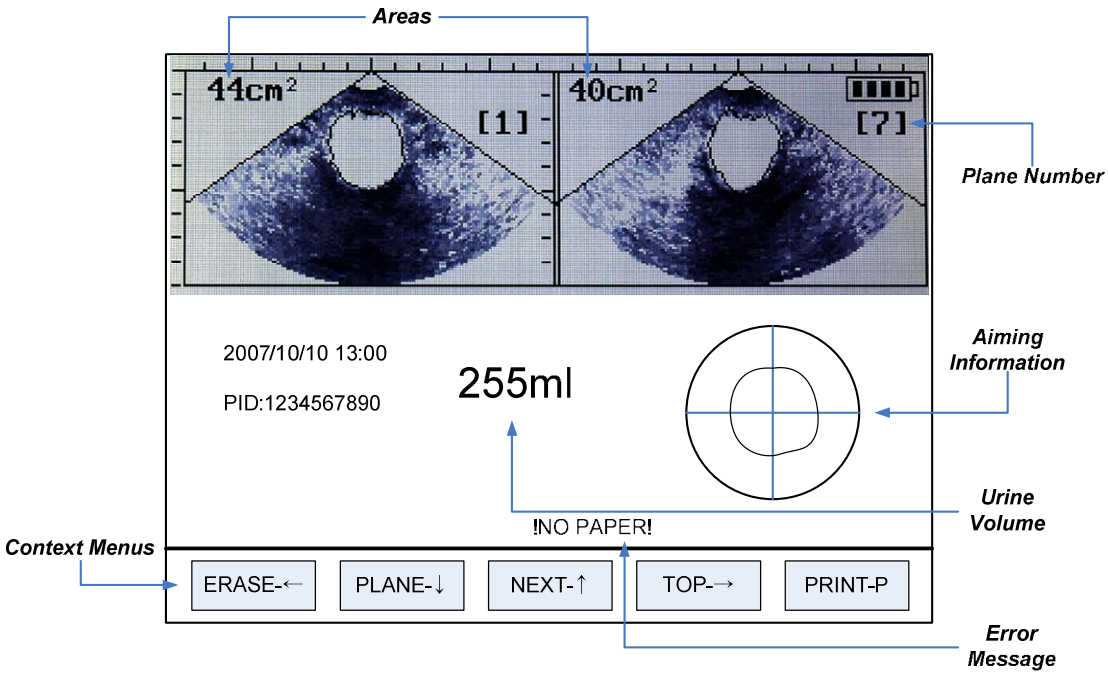


Fig 14 Load Screen

The following information will be displayed on the Load Screen

a) Two plane images
b) Areas for two planes images
c) Plane number
d) Measurement date & time
e) Patient ID
f) Urine Volume
g) Aiming information

*To review next saved data, press UP (*NEXT* option).

* To browse other planes press DOWN (*PLANE* option).

* To print current loaded data, press PRINT (*PRINT* option).

* To return to Top Screen, press RIGHT (*TOP* option).

* To erase current loaded data, press LEFT (*ERASE* option).

The following is an Erase Confirm Screen. In this screen to cancel, press LEFT (*CANCEL* option). To confirm the deletion of the current ,data, press PRINT (*CFIRM* option).

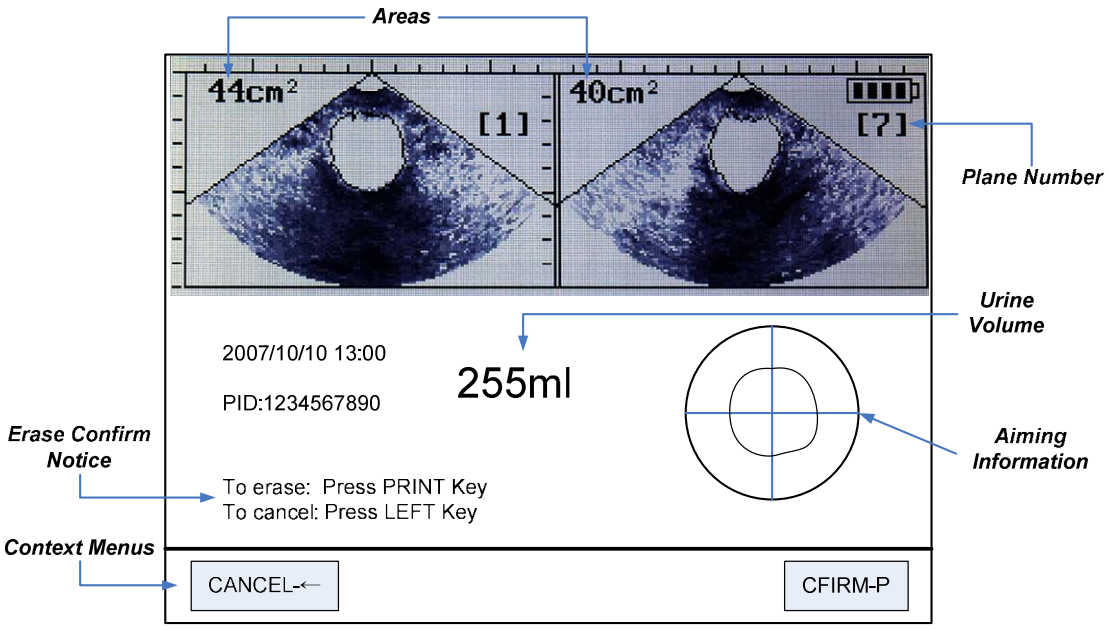


Fig 15 Erase Confirm Screen

5.6 Setting the Clinic Name

1) Press UP (*SETUP* option) on the Top Screen.

The Setup Screen will display as follows.

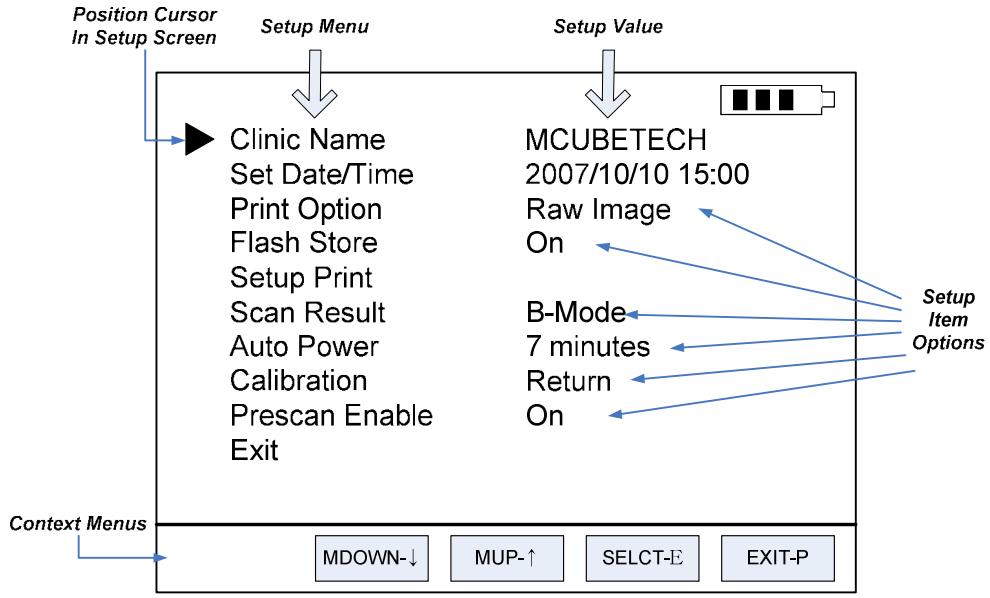


Fig 16 Setup Screen

2) With the selection cusor to the left of 'Clinic Name', press ENTER (*SELCT* option).

The Clinic Name Input Screen will be displayed as follows.

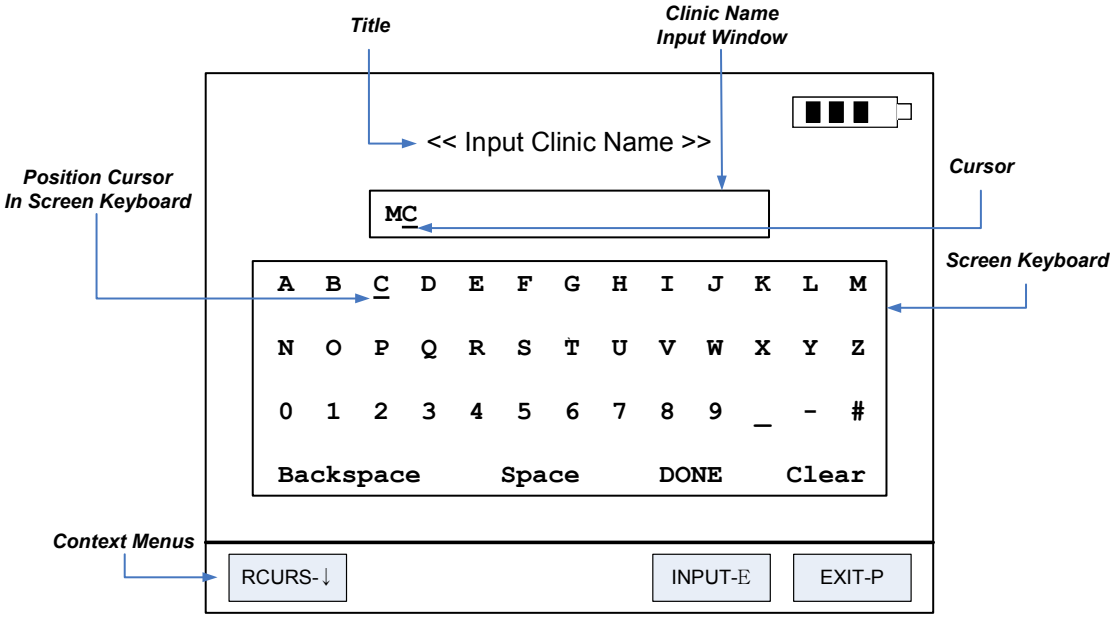


Fig 17 Clinic Name Input Screen

These items are displayed in the Clinic Name Input Screen,

a) Title '<<Input Clinic Name>>'
b) A Clinic Name Input Window
c) A Software Keyboard
d) And Contextual Menu Options

Within the software keyboard, the bottom 'keys' have special function.

Number	Screen Keyboard	Function
1	Backspace	Delete one character. Same function as backspace key on a computer's keyboard.
2	Space	Blank character.
3	DONE	Save the current clinic name shown in Clinic Name Input Window and return to Setup Screen.
4	Clear	Delete all characters in Clinic Name Input Window

3) Edit the clinic name by using the displayed keyboard..
To move around the keyboard use LEFT, UP, DOWN, RIGHT. These switches are not specified in Contextual Menu Options.

IMPORTANT:
- Pressing PRINT (*EXIT* option), will cause the system to return to the Setup Screen without saving the name.

4) After editing the clinic name, press ENTER with selection cursor under the DONE option on the keyboard.

5.7 Setting the Date & Time

1) Press UP (*SETUP* option) on the Top Screen.

2) With the selection cursor to the left of 'Set Data/Time', press ENTER (*SELCT* option).

The selection cursor in the Setup Screen will be moved to the right as shown below.

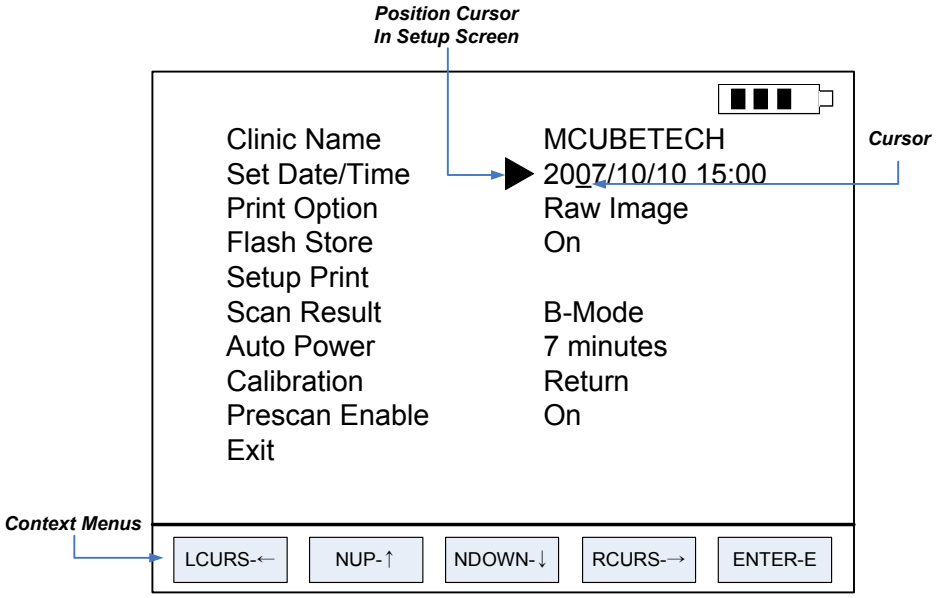


Fig 18 Setup Date/Time Screen

3) Changing the date and time is done through using the contextual options.

To move the cursor, use LEFT (*LCURS* option) or RIGHT (*RCURS* option).

To change the numeric data above the cursor use UP (*NUP* option), and DOWN (*NDOWN* option).

4) When done editing the date and time, save the changes using ENTER (*ENTER* option). The position curser will return to the left of the screen.

5.8 Customizing Other Setup Options

1) Press UP (*SETUP* option) on the Top Screen.

2) Move the position cursor using UP (*MUP* option) or DOWN (*MDOWN* option) to select the desired option.

3) Press ENTER (*SELCT* option).

The position cursor will move to the right of the selected item.

4) Browse the options by using LEFT (*OUP* option) or RIGHT (*ODOWN* option)

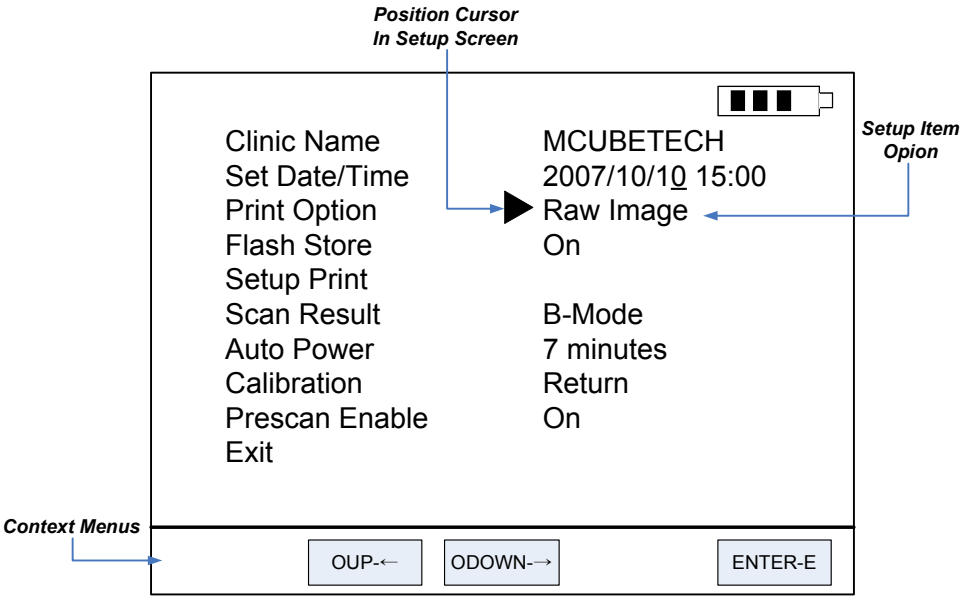


Fig 19 Setup Item Option Screen

5) Select setup item option ENTER (ENTER option).

Then the selection cursor moves to the left hand side of the Setup screen

The following table lists the customizable setup options

Setup Item	Option	Meaning
Print Option	Value Only	Print only the Urine volume
	Raw Image	Print the Urine volume, and all 12 planar images and bladder contour
	Walls	Print the Urine volume, and the contours of the 12 planes
	All Planes	Print the Urine volume and the images and bladder contours of all 12 planes
Flash Store	ON	To turn on the flash store function
	OFF	To turn off the flash store function
Scan Result	Contour	Show bladder outlines without images in the Scan Results Screen
	B-Mode	Show bladder outlines with images in the Scan Results Screen
Auto Power	Off	To turn off “auto power off”
	3 minutes	Turn the system off if there is no input for 3 minutes
	5 minutes	Turn the system off if there is no input for 5 minutes
	7 minutes	Turn the system off if there is no input for 7 minutes
	10 minutes	Turn the system off if there is no input for 10 minutes
Prescan Enable	ON	Turns on Pre-Scan functionality
	OFF	Turns off Pre-Scan functionality

5.9 Calibrating the BioCon-500 Using the Calibration Kit

5.9.1 Preparing the calibration kit

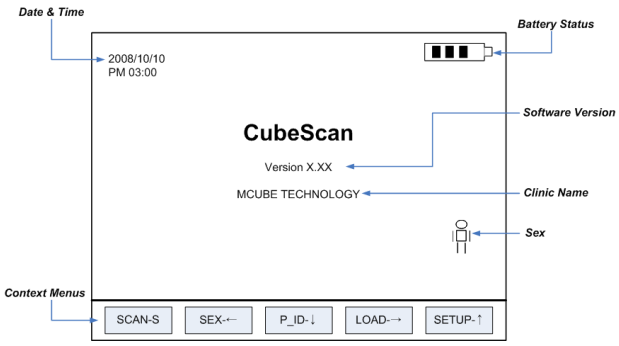
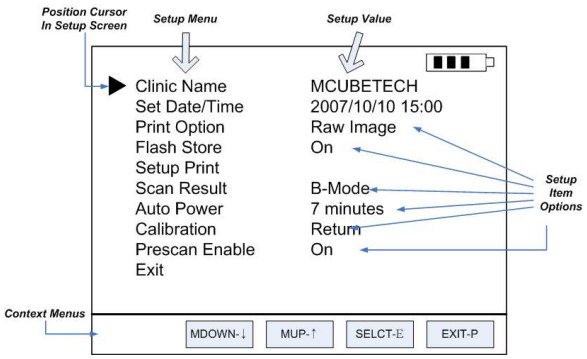
1) Open the cap of the calibration kit and pour 0.9 % saline solution up to the fill-mark of the calibration kit.
2) Close the cap.
3) Align the probe scan button with the arrow mark on the calibration kit, then insert the probe into the holder ensuring it is secure.

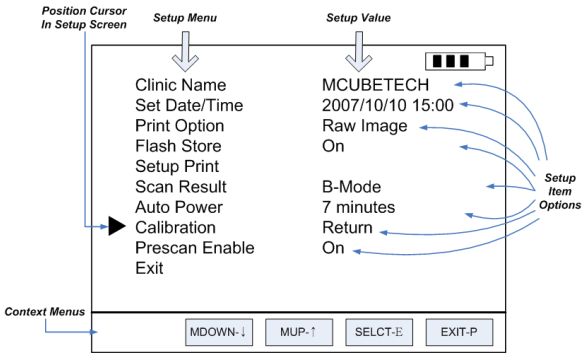
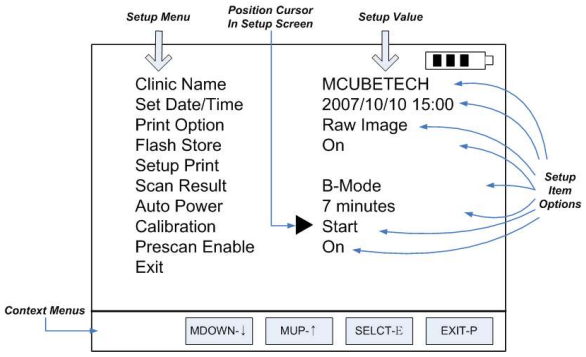
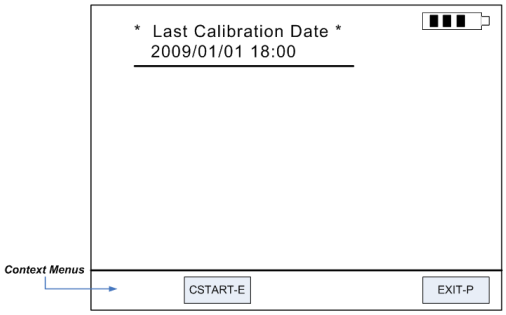
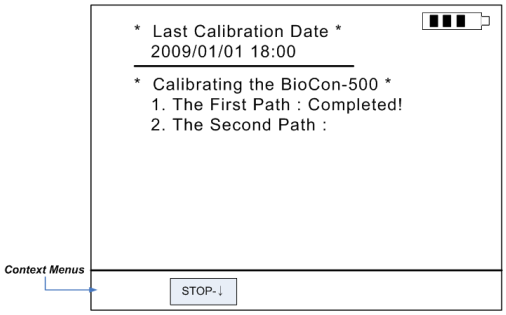
IMPORTANT:

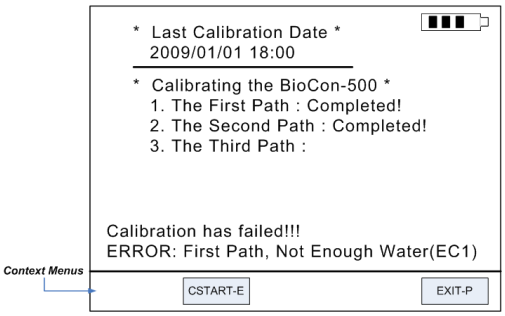
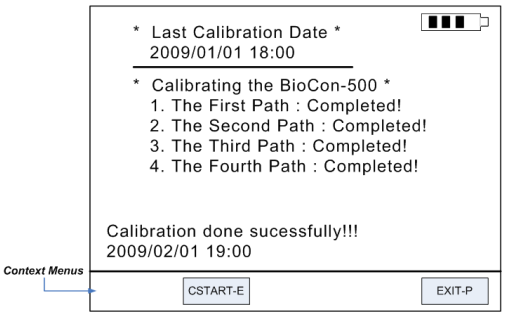
- Purge all air bubbles form the system.
- You can also use distilled or DI water instead of the saline. Purge the system of air bubbles in this case as well.

5.9.2 Calibrating the BioCon-500 with the calibration kit

1) Connect the probe which is positioned into the probe holder of the calibration kit to the console
2) Turn on the console

Screen Display in the BioCon-500	Description
	The Top Screen. Press **UP** to go to setup menu.
	Setup Menu Go to “Calibration” setup using **UP** or **DOWN**.

	Press **ENTER** key.
	Select the “Start” setup value using **LEFT** or **RIGHT**.
	Calibration top screen To start calibration, press **ENTER**.
	Screen during calibration. To stop the calibration process, press **DOWN** in the first path or second path. In the third path and fourth path, a user cannot interrupt the calibration.

	If there are any errors during calibration, the main display will show the message “Calibration has failed!!!” “ERROR: First Path, Not Enough Water(EC1)”. In the error message, “First Path” means the calibration steps when the system detected any error during calibration. “Not Enough Water” means additive information about the error state. This additive information is displayed for only EC1 error. “EC1” means the error code during calibration.
	The screen when the calibration is done successfully. The date and time when the calibration is done successfully is displayed in the bottom part of the LCD screen.

IMPORTANT:

- The BioCon-500 returns to the top screen when the calibration process is terminated or stopped.
- To leave the calibration screen, press the down key (only effective in the first and second path of the calibration process) for more than 5 seconds or turn off the system by pressing the power key.

5.10 Buttons and their Contextual Menu Abbreviations

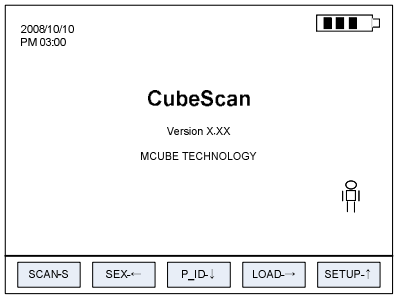
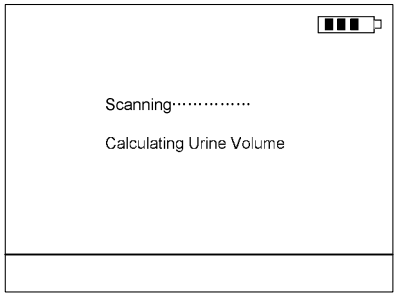
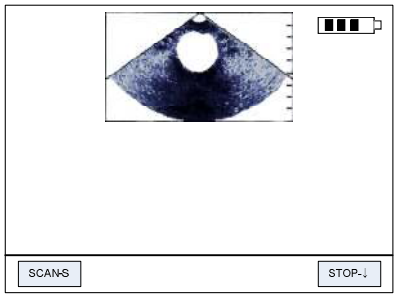
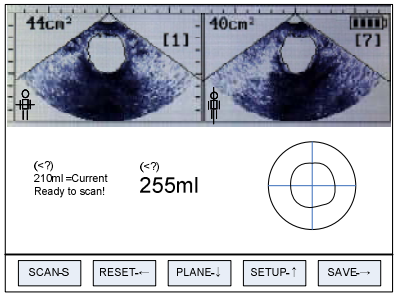
The context menus in bottom line of the display is shown like this – ENTER-E *ENTER* is a context menu and E is the abbreviation for the button to press to activate the *ENTER* option.

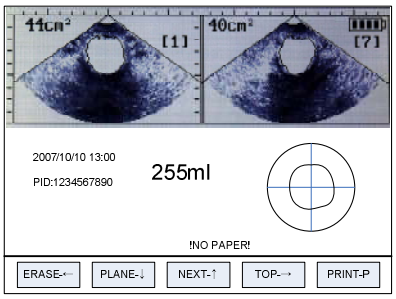
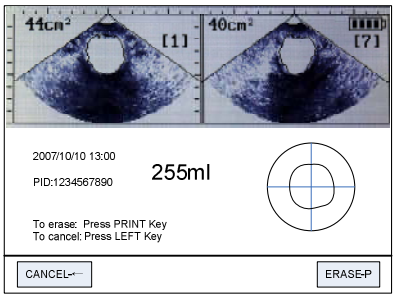
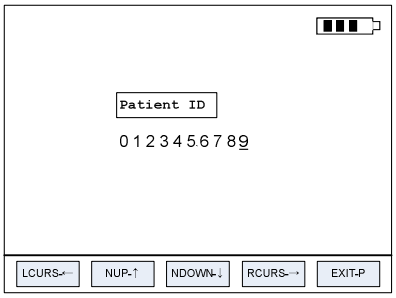
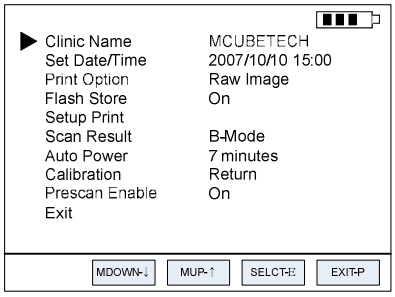
Tactile switch	Abbreviation in context menu
SCAN	S
PRINT	P
LEFT	←
UP	↑
DOWN	↓
RIGHT	→
ENTER	E

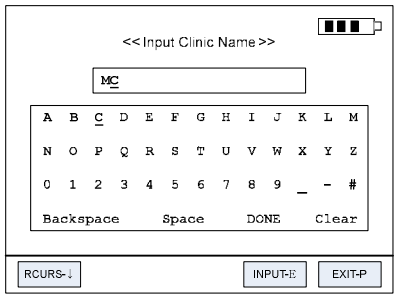
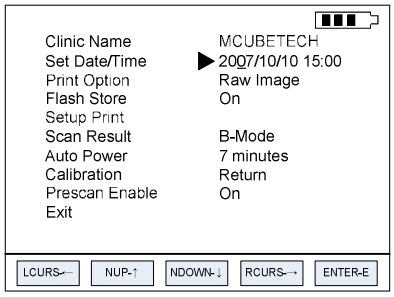
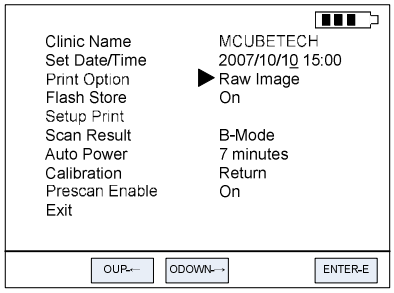
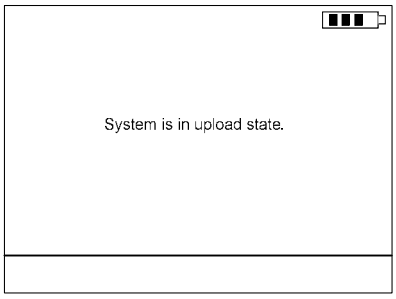
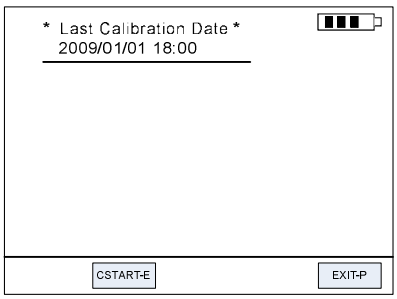
* The membrane button on the probe has the same function as the SCAN button.

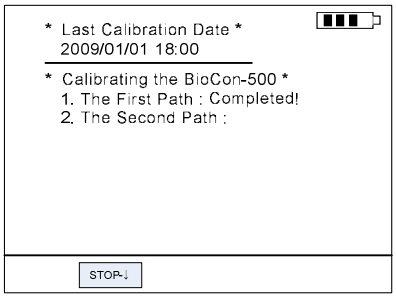
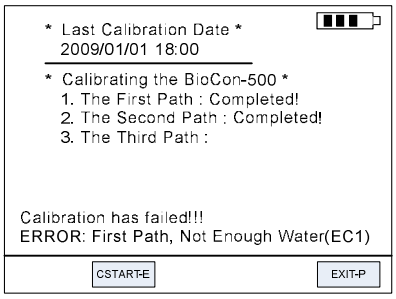
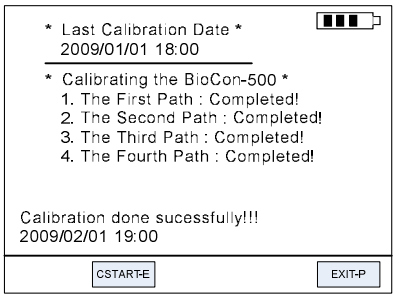
5.11 Summary of Each Screen and its Context Menus

Following table summarizes each screen's contextual menus in the system.

Name	Screen	Menu	Function
Top Screen		*SCAN*	Start Pre-Scan or normal scan in a new session.
		SEX	Change the patient type.
		P_ID	To change the patient ID, goes to the Patient ID Input Screen.
		LOAD	To review saved data, goes to the Load Screen.
		SETUP	To setup system options, goes to the Setup Screen.
During Scanning		-	-
Pre-Scan Screen		*SCAN*	Activate the normal scan.
		STOP	Stop the Pre-Scan and return to the Top Screen.
Scan Results Screen		*SCAN*	Start Pre-Scan or normal scan in the current session.
		RESET	Exit the current session and return to the Top Screen
		PLANE	Displays the next two plane images.
		SETUP	Goes to the Setup Screen.
		SAVE	Saves the results of the current session.

Load Screen		*ERASE*	Goes to the Erase Confirm Screen.
		PLANE	Displays the next two plane images.
		NEXT	Display next saved session..
		TOP	Return to the Top Screen.
		PRINT	Print the current data.
Erase Confirm Screen		*CANCEL*	Cancel the erasure.
		ERASE	Erase current saved session data.
Patient ID Input Screen		*LCURS*	Move the selection cursor to the left.
		NUP	Increase the value above the cursor.
		NDOWN	Decrease over the value above the cursor.
		RCURS	Move the selectrion cursor to the right.
		EXIT	Return to the Top Screen.
Setup Screen		*MDOWN*	Move the selection cursor downward.
		MUP	Move the selection cursor upward.
		SELCT	Select the current option for customization.
		EXIT	Return to the Top Screen.

Clinic Name Input Screen		*RCURS*	Move the selection cursor to the right.
		INPUT	Select the letter above the selection cursor.
		EXIT	Return to the Setup Screen.
Setup Date/Time		*LCURS*	Move the selection cursor to the left.
		NUP	Increase the value above the cursor.
		NDOWN	Decrease over the value above the cursor.
		RCURS	Move the cursor to the right.
		ENTER	Save the date and time.
Other Options' Setup		*OUP*	Browse to the next option upward.
		ODOWN	Browse to the next option downward.
		ENTER	Set the option to currently displayed value.
Upload Screen			IMPORTANT: "Upload Screen" will be shown during upload the data to the computer. There is no active menu in Upload Screen.
Setup Calibration Top Screen		*CSTART*	Start calibration.
		EXIT	Return to the Top Screen.

Setup Calibrating Screen		*STOP*	Stop the calibration process. A user can stop the calibration during step 1 and step 2. Press and hold DOWN for more than 5 seconds to stop calibration.
Setup Calibration Error Screen		*CSTART*	Retry the calibration process over.
		EXIT	Return to the Top Screen.
Setup Calibration Completion Screen		*CSTART*	Retry the calibration process over.
		EXIT	Return to the Top Screen.

5.12 Summary of Menus not Shown on Context Menus

There are menus which were not shown on context menus but have its function in that screen. Following table summarizes those menus and their functions in each screen.

Screen	Option	Button	Function
Scan Results Screen	*PRINT*	PRINT	Print the results of the current session.
Clinic Name Input Screen	*MLEFT*	LEFT	Move the selection cursor to the left.
	MRIT	RIGHT	Move the selection cursor to the right
	MUP	UP	Move the selection cursor up
	MDOWN	DOWN	Move the selection cursor down

6 THE OPTIONAL SOFTWARE(CubeScanPC)

Skip this part if you do not have or use the optional CubeScanPC software.

6.1 General Information

Copyright ⓒ 2007 Mcube Technology Co., Ltd. All rights reserved.
The contents of this manual are the property of Mcube Technology Co., Ltd. Any reproduction in whole or in part is strictly prohibited.
This manual correctly describes the software and its functions at the time of publishing of the CD-ROM. However, as modifications may have been carried out since the production of this manual, the device package may contain one or more addenda to the manual. This manual including any such addenda must be read, before using the software.
The following situations void any guarantee(s) and obligations of Mcube Technology:
- The software is not used according to the enclosed manuals and other accompanying documentation.
- The software is installed or modified by persons other than Mcube Technology certified service technicians

**** "SETTING UP The BioCon-500™"** function is only available to service engineers and technicians**.**

This User Guide covers the basics of installing CubeScanPC software and using the upload function between the **BioCon-500™** and a PC.
The following information is covered in this manual.

- Warning statements.
- Intended use.
- PC requirements.
- Installation
- Operation
- Technical data

6.2 Intended Use

This CubeScanPC software is intended to allow scan image data to be uploaded to a PC from the BioCon 500.. The uploaded scan data may be reviewed, maintained, and filed on a PC. Additionally it may be printed from a PC.

BioCon-500™

The **BioCon-500™** is a B-mode ultrasonic device that is intended for the measurement of residual urine volume. The device automatically calculates the volume using ultrasound images from a three-dimensional sector probe. The **BioCon-500™** saves scan image data for up to 5 sessions.

6.3 Installing CubeScanPC Software

6.3.1 PC Requirements

Recommended PC requirements are as follows.

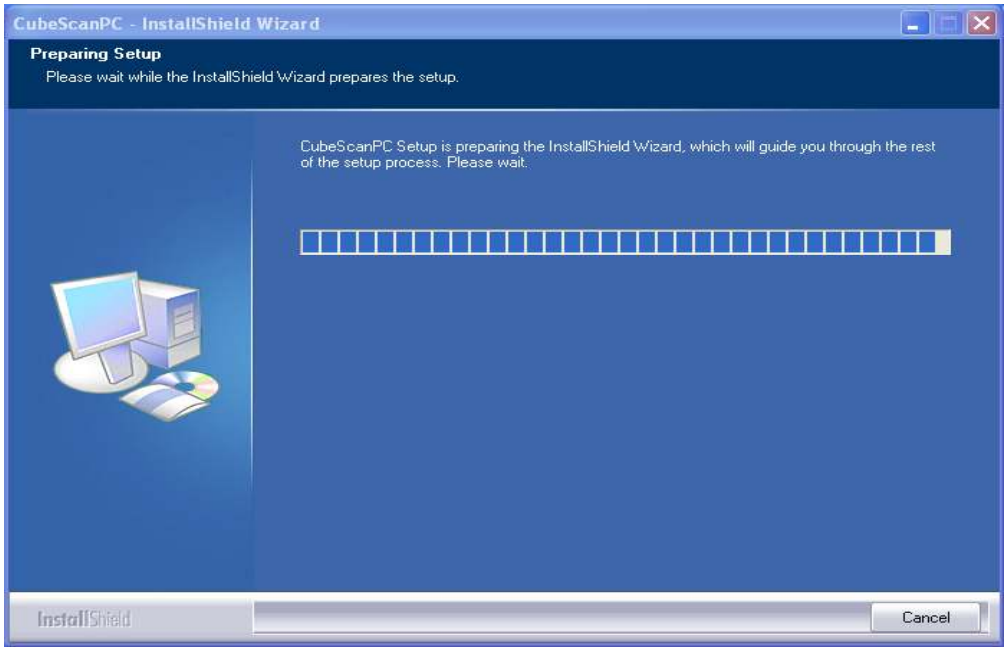
- Operating system: Windows XP
- Processor: Pentium III, 500MHz (minimum).
- Main memory: 256MB (minimum).
- Hard disk: minimum 100MB free space.
- CD-ROM: minimum 10x.
- Monitor Resolution: minimum 1024*768.
- Keyboard and Mouse
- USB port: USB1.1 or USB 2.0

IMPORTANT:

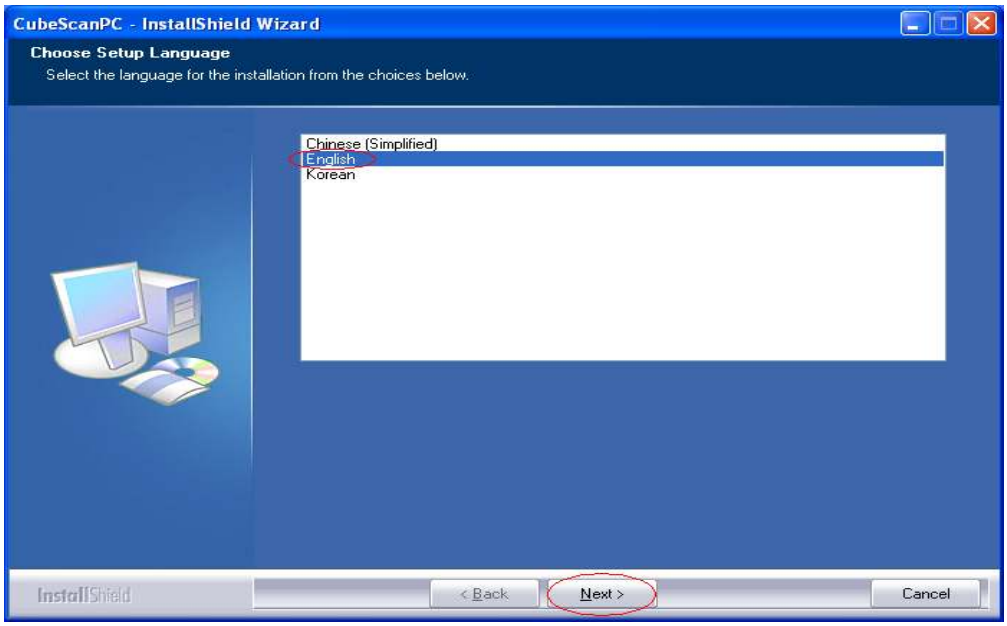
- There is an additional need of about 282KB of storage space for each session's scan data.

6.3.2 Installing Software

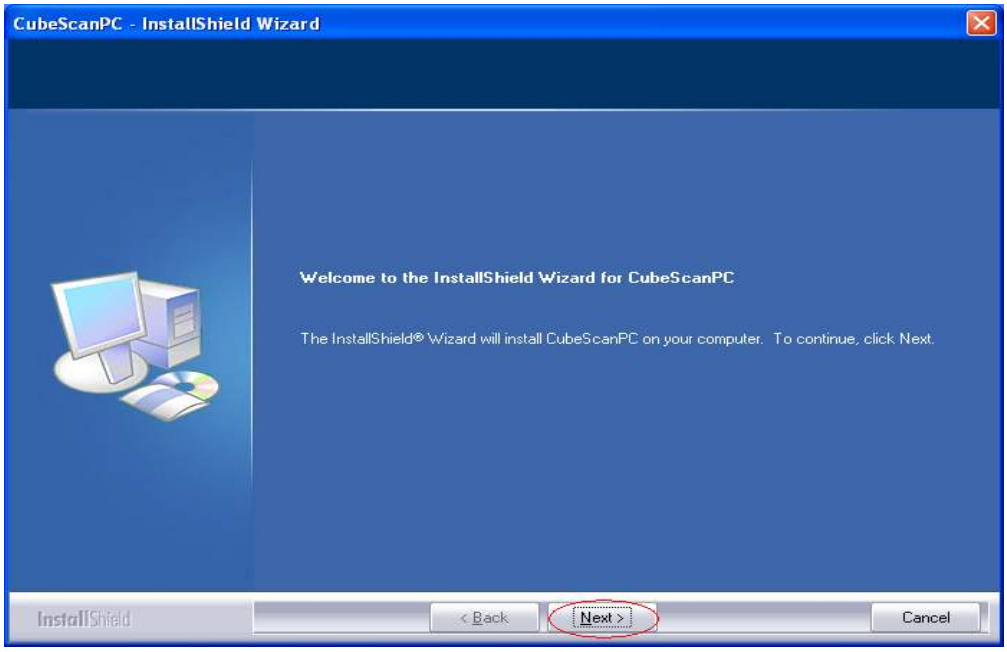
1) Insert the software CD into the CD-ROM drive.
2) Double click *CubeScanPC_Setup.exe* file in the root folder of the CD.
   a) Preparing setup dialog will be displayed as follows.



   b) Choose setup language and click Next.

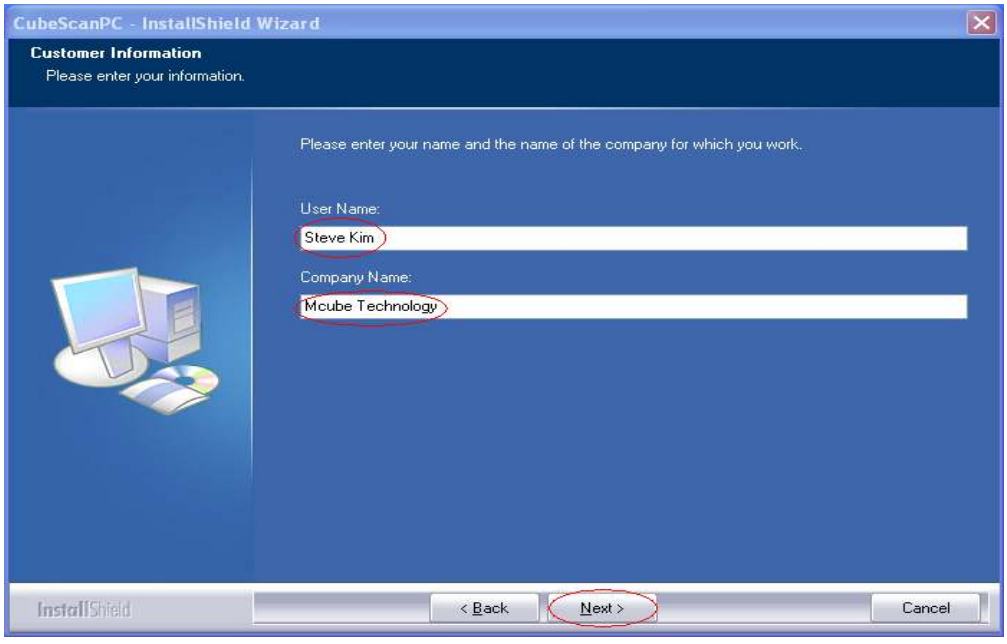


c) Initial screen for installation - Click Next.



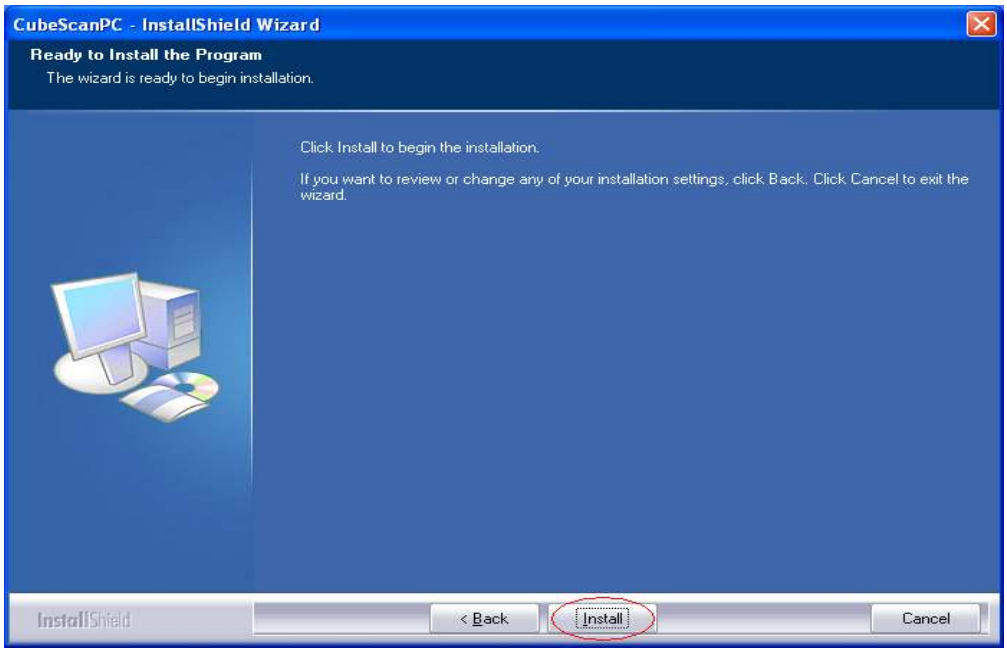
d) Customer Information Dialog

- Please enter your name and company name.
- Then click Next.

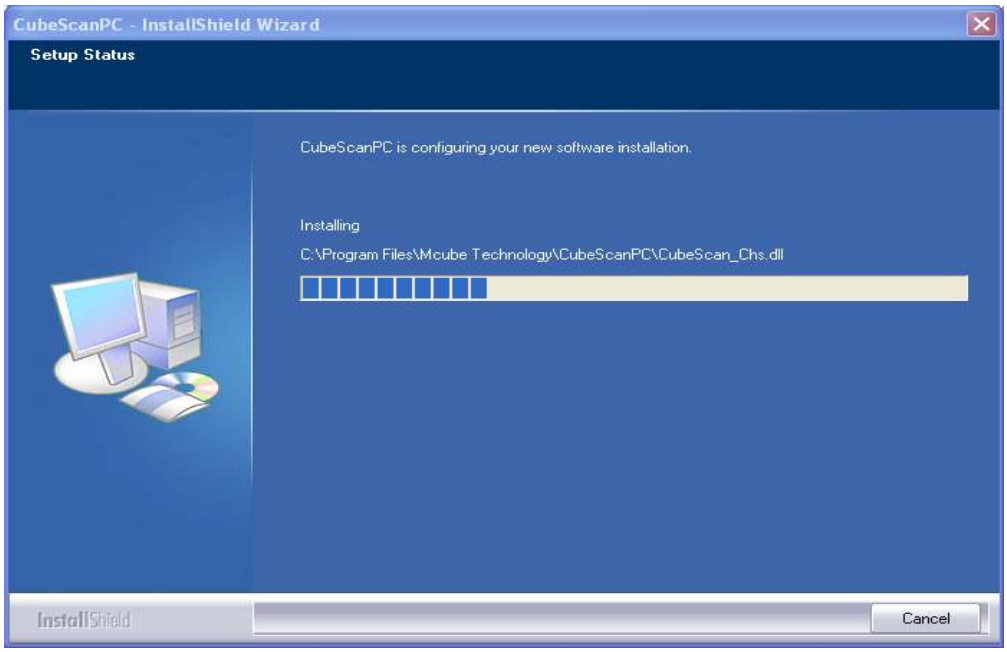


e) Ready to start Installation.

- You are ready to start installation. Click Install to continue.

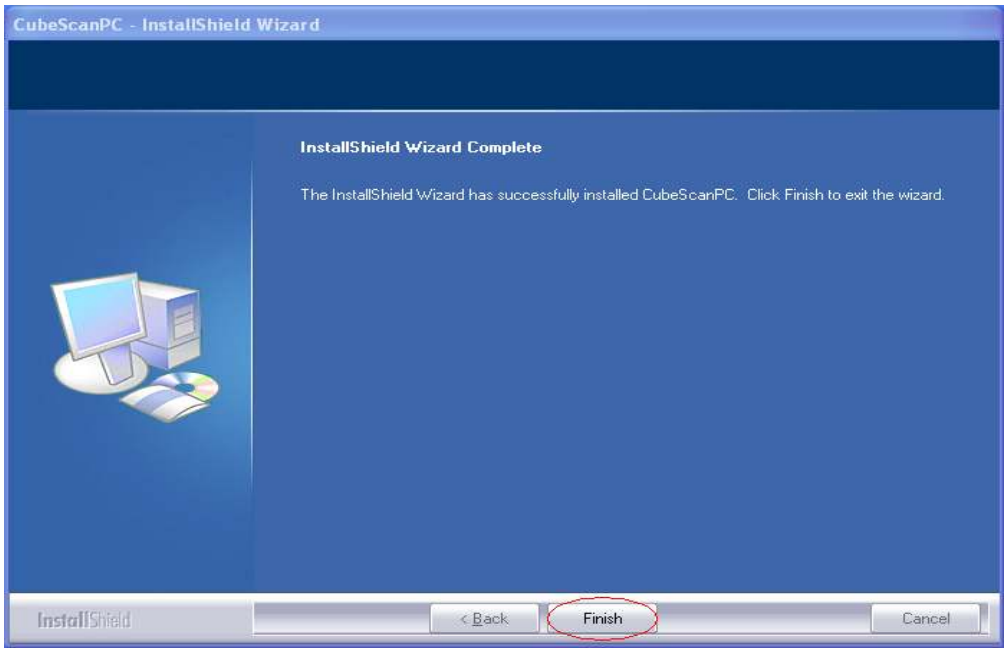


f) Setup status dialog will be displayed during installation as follows.



g) Finish dialog.

- Setup is successfully completed. Click Finish.



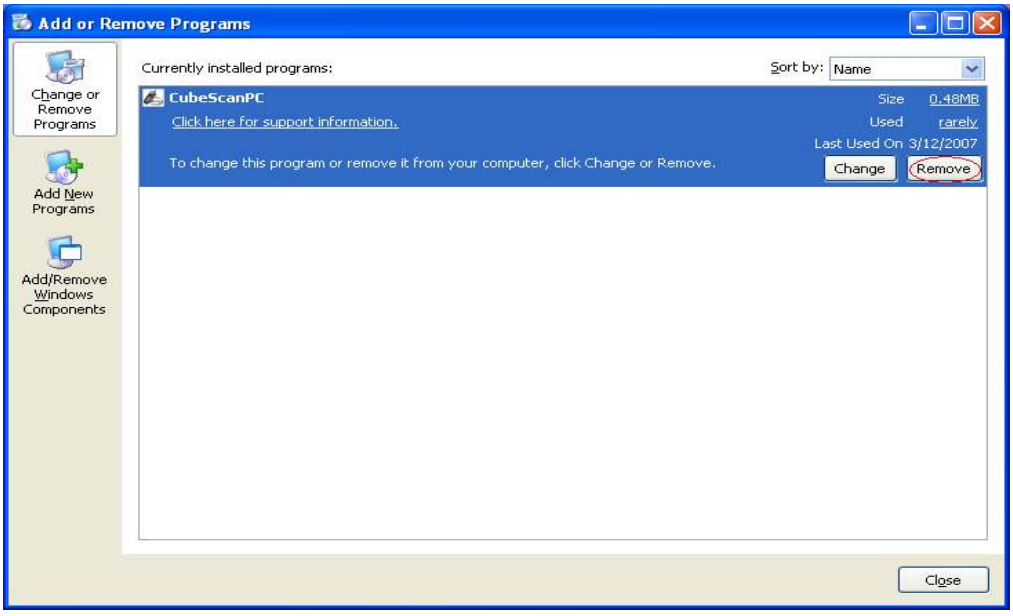
6.4 Uninstalling Software

1) Click on start in Windows.

2) Click control panel.

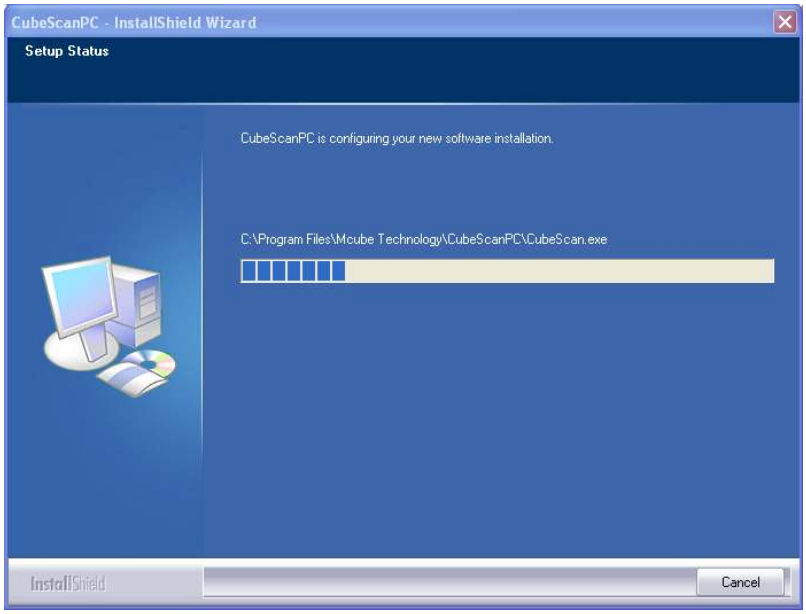
3) Click Add or Remove Programs in control panel.

4) Click Remove for remove of CubeScanPC program.

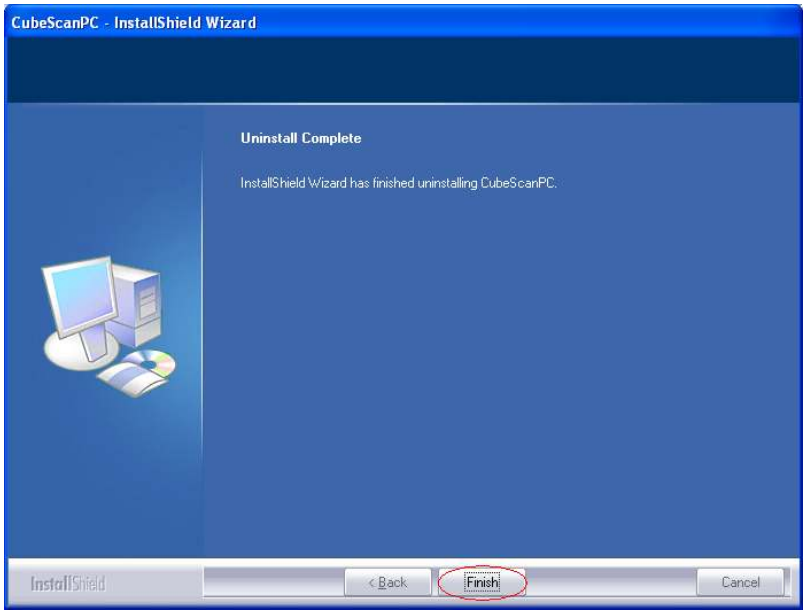


5) To confirm, click Yes.

6) Status dialog will be displayed as follows.



7) To finish, click Finish.



6.5 Device Description

6.5.1 Parts Lists

Parts list included along with this software is as below:

- This User Guide
- 1 CD with CubeScanPC Software
- 1 USB cable

6.5.2 System Schematics

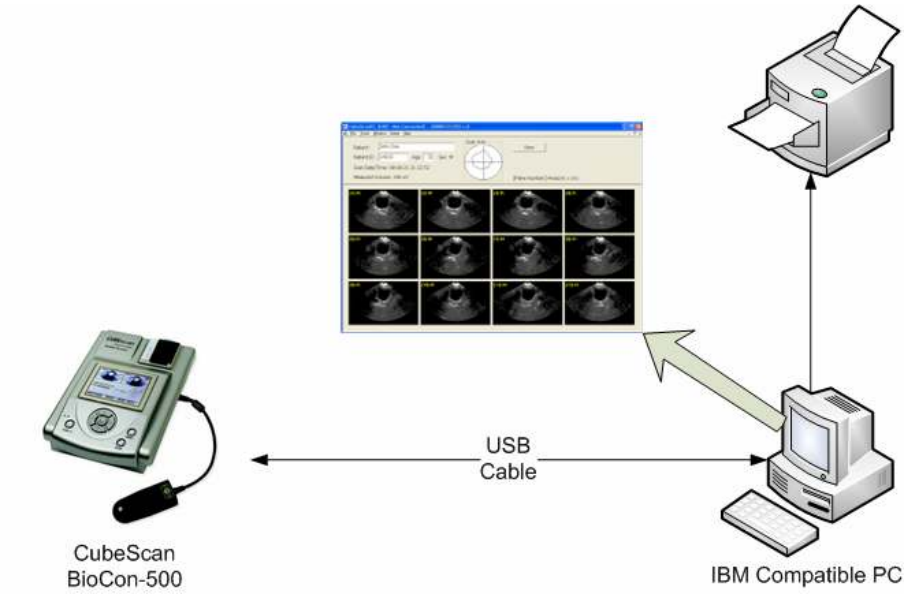


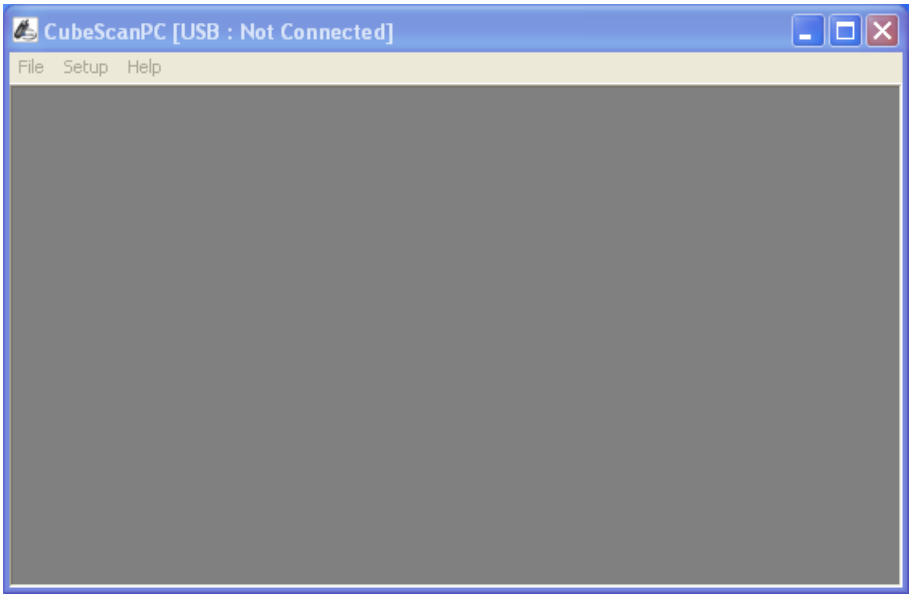
Fig 20 System Schematics

6.6 Getting Started

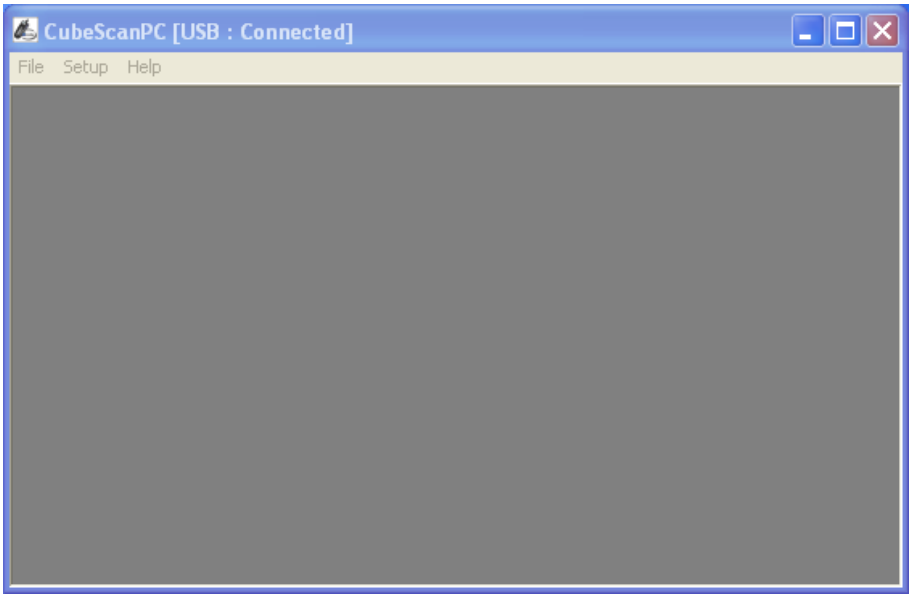
Connecting to the **BioCon-500™**.

1) Connect the **BioCon-500™** with a USB cable to a PC while the **BioCon-500™** is powered-off.
2) Click START button of Windows.
3) Click ALL PROGRAM
4) Click Mcube Technology
5) Click CubeScanPC

The initial screen is shown below:



6) Turn the **BioCon-500™** on. After powering-on, the program's title bar should be changed into as below (USB:Connected):



WARNING:

- If there is no sign of connection after the **BioCon-500™** has been powered on for more 1 minute, make sure that the connections are correct and secure and retry. If there is still no message of connection, the device may need servicing..

7) The connection is established when the USB state is 'Connected'.

6.7 Use of the Software

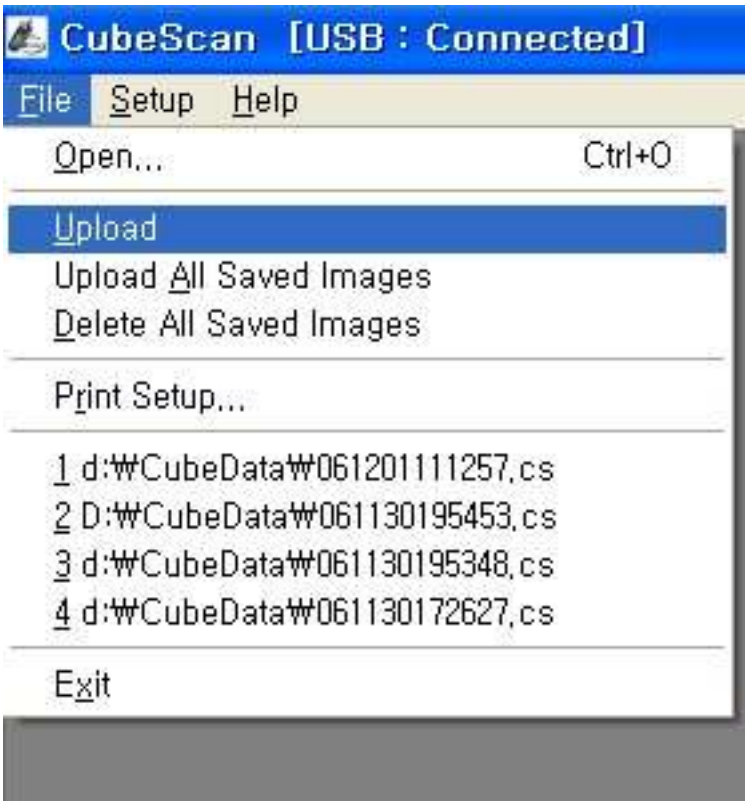
6.7.1 Upload the Scan Data

This function is used to transfer session scan data from the **BioCon-500™**.

1) Check the connection status between PC and the **BioCon-500™** in title bar. It should read “USB : Connected”

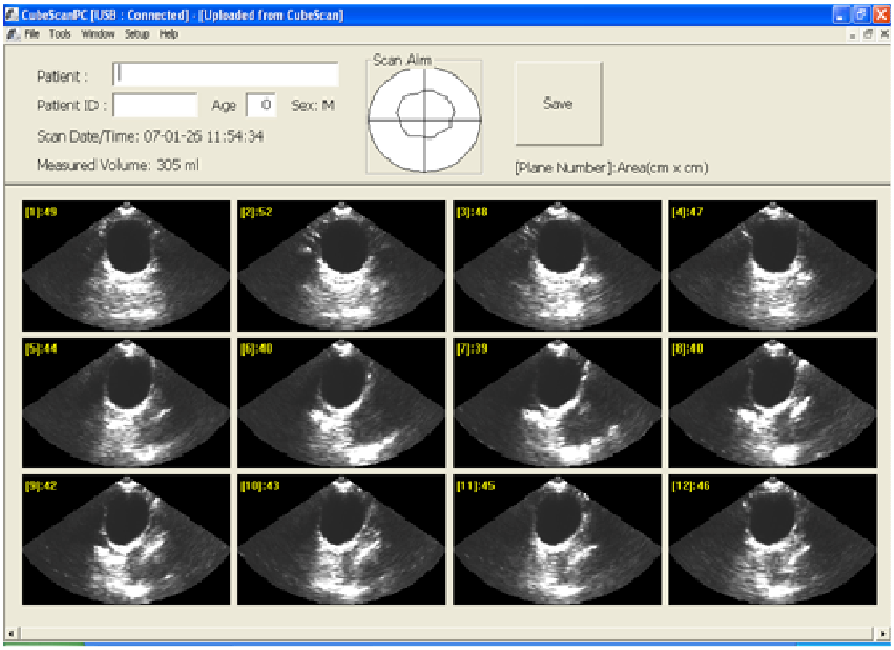
2) Click File in a menu bar.

3) Click Upload.

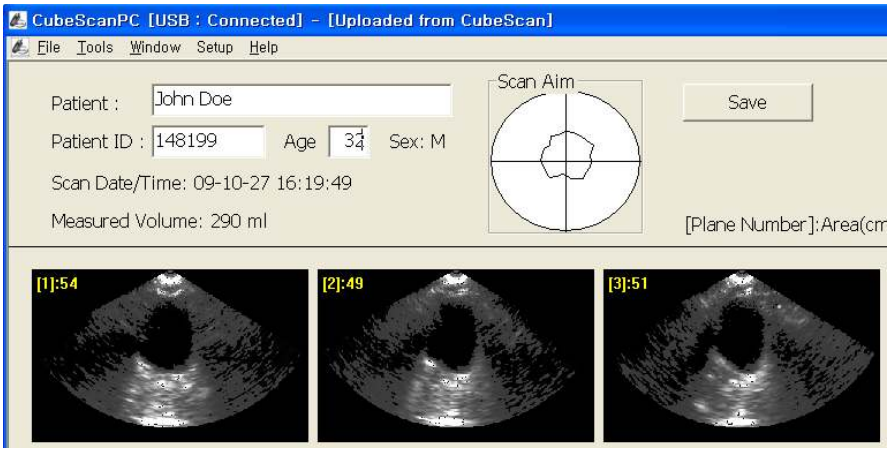


4) During upload, a status dialog will display the progress of the upload.

5) When completed, the data will be displayed on the PC as follows.



6) Enter the patient information and save the contents using Save button.



7) Refer to *Printing the Scan Data* for printing.

IMPORTANT:

- If the **BioCon-500™** is powered off without saving the scan data into the flash rom, it will not be saved and will be lost Be sure to save the data that is intended to be uploaded to a PC.

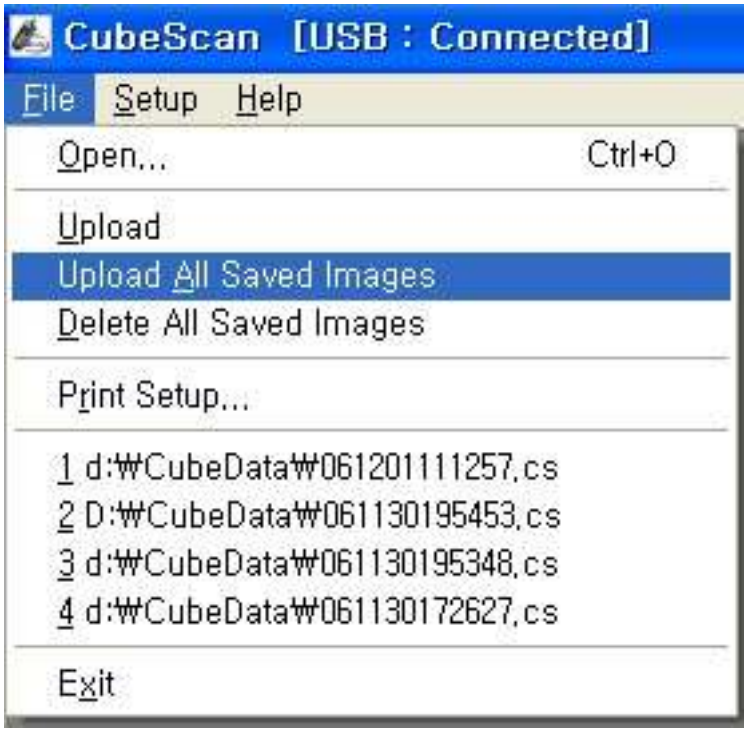
6.7.2 Upload All Saved Scan Data

This function is used to upload all the stored data in flash memory.

1) Check the connection status between PC and the **BioCon-500™** in title bar.

2) Click File in a menu bar.

3) Click Upload All Saved Images.



4) During upload a status dialog will display the progress of the upload

5) When completed, the data will be displayed on the PC as shown in the single upload case. In the multiple upload case, each session will have a dedicated window.

6) Enter the patient information and save the contents using Save button for each window open

The **BioCon-500™** can store up to 5 scanning sessions

7) Refer to *Printing the Scan Data* for printing.

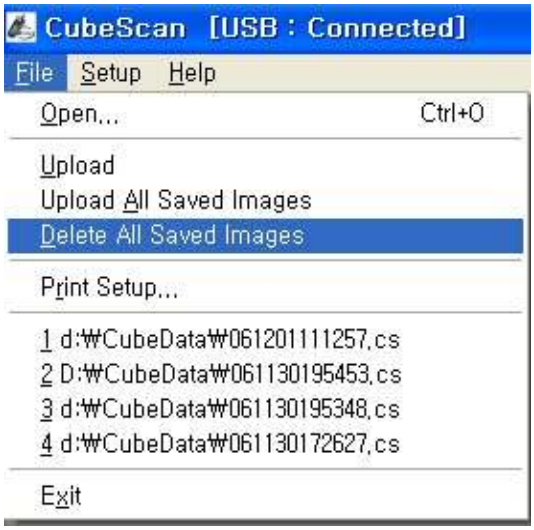
6.7.3 Deleting All Saved Scan Data

This function is used to delete all saved data in the **BioCon-500™**.

1) Check the connection status between PC and the **BioCon-500™** in title bar.

2) Click File in menu bar.

3) Click Delete All Saved Images.



4) Dialog box for confirmation is presented.

When you press Yes, all stored data will be deleted.

IMPORTANT:

- Functionality that deletes individual stored datum is not yet implemented.

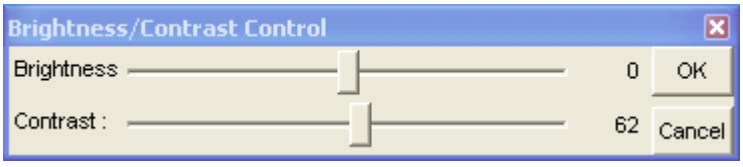
6.7.4 Contrast/Brightness Control

Modifies the contrast and brightness of the image.

1) Click on Tools in the menu bar.

2) Select Brightness/Contrast

3) A dialog box will display allowing for the adjustment of the brightness and contrast.



Use the slider bars to adjust the brightness and contrast using either a mouse or the keyboard's arrow keys.

IMPORTANT: | ● Tools menu is only available if a data file is open

6.7.5 Changing Image Size

This function is used to modify the size of displayed image. Available sizes are 50%, 75%, 100% and 200%

1) Click on Tools in the menu bar.

2) Select Image Size.

3) Click on the desired size

IMPORTANT: | ● Images will always print at 100%. This will not impact the print size

6.7.6 Printing the Scan Data

This function is used to print scan data from a PC to a printer.

1) Click on File in the menu bar.

2) Select the desired printer

3) Click Print.

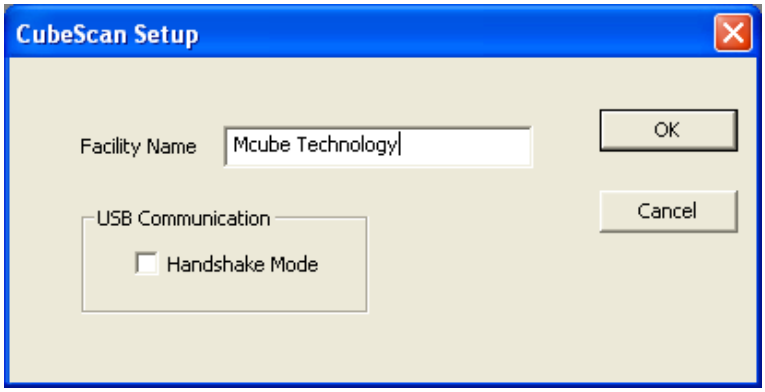
IMPORTANT: | ● You can preview the layout through the Print Preview in the menu bar

6.8 Setting up CubeScanPC

This is used to change the CubeScanPC's software settings. The only available function is to input the Facility Name.

6.8.1 Facility Name

1) Click *Setup* in the menu bar.
2) Select *CubeScanPC Setup.*



3) CubeScanPC Setup Dialog is displayed. Enter the desired facility name.
4) Click ***OK***.

* "Handshake Mode" does not have any effect on the operation of the CubeScanPC Software currently.

IMPORTANT:

- Facility name used here is independent of the one in Device Configuration menu and is only used for printing purposes. Facility name in Device Configuration is saved in the **BioCon-500™** and not impacted by this option.

7 TROUBLESHOOTING

7.1 Troubleshooting

Error message	Description	Actions
BATTERY LOW!!!	**Battery low**	Use again after charging the battery. **IMPORTANT:** To lengthen the lifetime of the battery, charge the battery when it is around 20% charged.
NO PAPER!	**Printer Error**	1. Ensure the printer cover is closed. If the cover is open, close the cover and try printing again. 2. Check if the thermal paper is empty. If there is no paper, insert a new roll of paper and try printing again. 3. If the above steps do not successfully solve the problem, contact an authorized servicer.
NO SCANHEAD	**Connection Error**	Check if the connection between the probe and the console is secure. If the above does not successfully solve the problem, contact an authorized servicer.
ERROR IN CABLE CONNECTION!	**Transducer circuit open**	Contact an authorized servicer..

8 MAINTENANCE

8.1 Battery Care

Do not overcharge the battery and avoid deep discharges. To lengthen the battery's lifetime, use the system while the battery is between 25%~75%.

The **BioCon-500™** does draw power from the battery even while powered off. To avoid deep discharge, disconnect the battery from the system if it will not be used for more than a week. When storing the battery, pre-charging to about 75% is recommended.

8.2 Changing the Battery Modules

See 4.1 "Installing or removing battery"

8.3 Changing the Thermal Paper

See 4.2 "Changing the thermal paper"

8.4 Cleaning & Disinfection

8.4.1 Cleaning

1) Cleaning outer case (housing) of the system

a) Wipe the main body using soft cloth dampened with isopropyl alcohol or any other appropriate hospital cleaning solution.. Do not allow liquids to leak into the device while cleaning..

b) Thoroughly dry the device with a clean, soft cloth before re-deployment.

2) Cleaning the probe

Cleaning the surface of the Probe;

a) Disconnect the Probe from the system.

b) Wipe the probe cap using a soft cloth dampened with isopropyl alcohol or an appropriate hospital cleaning agent.

c) Then wipe with water-dampened cloth.

d) Dry with a soft, clean cloth.

WARNING:

- To avoid electric shock disconnect the system from the AC mains and the battery.

CAUTION:	● Do not immerse the console or the probe. ● Do not use harsh, corrosive chemicals (e.g. hydrochloric acid, bleach).

8.4.2 Disinfection

1) Disinfection of the Probe

a) Clean the Probe prior to disinfection.

b) Dampen a soft cloth with disinfected solution listed in the table below.

c) Wipe the probe with a dampened cloth.

d) Air dry or towel dry with a soft, clean cloth.

e) Inspect the Probe and the cable for any damage such as cracks.

WARNING:	● To avoid electric shock disconnect the system from the AC mains and the battery
CAUTION:	● Do not immerse the console or the probe.

Disinfectants Lists for the Probe disinfection

Use any glutaraldehyde based disinfectant to disinfect the Probe. Following table lists compatible disinfectants.

Disinfection Solutions	Type	Country of Origin	Manufacturer
Cidex	Liquid	USA	Johnson & Johnson
Cidex 7	Liquid	USA	Johnson & Johnson
Metricide 14	Liquid	USA	Metrex Research Inc.
Metricide 28	Liquid	USA	Metrex Research Inc.

CAUTION:	● Do not use Cidex Plus or Metricide Plus 30 to disinfect the device. Cidex Plus or Metricide Plus 30 will attack and damage the plastic enclosure. This will be considered as abuse and will void the warranty.

8.5 Weekly Inspection

a) Try to scan with the probe disconnected, check if the "**NO SCANHEAD**" message is displayed on the main display.

b) Thoroughly inspect the probe for cracks or leakage.

c) Inspect the probe cable for any damage.

d) When scanning, check for any abnormal noise emanating from the probe head.

8.6 Device Repair

Faults not described in section "7. Troubleshooting" are intended to be serviced by a certified technician. In the event a situation outside of those described in the section occurs, contact an authorized servicer or Mcube Technology for servicing.

8.7 Disposal

The device and accessories may contain environmentally hazardous materials (mineral oil, lead, battery pack, etc). When they have reached the end of its useful service life, return them to the Mcube Technology, or follow your local regulations for hazardous waste disposal.

9 SPECIFICATIONS

9.1 Symbol Directory

Symbol	Description
	Type BF patient applied part (B= body, F= floating applied part)
	Attention, see the User manual.
	Direct current(DC)
	Alternating current(AC)
IPX1	Degrees of protection against the ingress of water.
CE 0120	CE marked in accordance with the Medical Device Directive
	UL classification mark for Canada and the U.S.
	Collect separately from other household waste (see European Commission Directive 93/86/EEC). Refer to local regulations for disposal.
	Date of manufacture
REF	Reference number
SN	Serial number

9.2 Acoustic Output Table

Transducer Model: 2.8MHz Transducer **Operating Mode: B-mode**

Index Label				MI	TIS			TIB	TIC
					scan	non-scan		non-scan	
						Aaprt≤1	Aaprt>1		
Global Maximum Index Value:				0.307	0.002	X	X	X	0.002
	IEC	FDA	Units						
Associated Acoustic Parameter	p_{ra}	$p_{r.3}$	(MPa)	0.50					
	P	W_o	(mW)		0.13	X		X	0.13
	min of $[P_\alpha(z_s), I_{ta,\alpha}(z_s)]$	$[W_{.3}(z_1), I_{TA.3}(z_1)]$					**X**		
	z_s	z_1	(cm)				X		
	z_{bp}	z_{bp}	(cm)				X		
	z_b	z_{sp}	(cm)					X	
	z *at max.* Ipi, α	z_{sp}	(cm)	4.70					
	$d_{eq}(z_b)$	deq(z_{sp})	(cm)					X	
	f_{awf}	f_c	(MHz)	2.63	2.63	X	X	X	**2.63**
	Dim of Aaprt	X	(cm)		1.40	X	X	X	1.40
		Y	(cm)		1.40	X	X	X	**1.40**
Other Information	t_d	PD	(μsec)	0.77					
	prr	PRF	(Hz)	400.00					
	p_r *at max.* I_{pi}	p_r@PII$_{max}$	(MPa)	0.49					
	d_{eq} *at max.* I_{pi}	d_{eq}@PII$_{max}$	(cm)					X	
	Focal Length	FL_X	(cm)		7.60	X	X		7.60
		FL_Y	(cm)		7.60	X	X		7.60
	Ipa, α *at max. MI*	$I_{PA.3}$@MI$_{max}$	(W/cm^2)	3.73					
Operating Control Conditions	**Frequency**			2.80	2.80	X	X	X	2.80
	…								

Notes: (a) This index is not required for this operating mode; see section 4.1.3.1 of NEMA Standard UD-3.

(b) This probe is not intended for transcranial or neonatal cephalic uses.

(c) This formulation for TIS is less than that for an alternate formulation in this mode.

No data are reported for this operating condition since the global maximum index value is not reported for the reason listed.

Acoustic Measurement Precision and Uncertainty

All entries in the below table have been obtained at the same operating conditions that produce the maximum index value. The measurement precision and uncertainty values are determined by repeated measurements.

Parameter	Precision (% of standard deviation)	Uncertainty (95%)
$p_{r.3}$	5.4%	±21%
W_o	6.2%	±28%
f_c	4.8%	±14%

9.3 Definitions and symbols

MI	the Mechanical Index
TIS_{scan}	the Soft Tissue Thermal Index in an auto-scanning mode
$TIS_{non-scan}$	the Soft Tissue Thermal Index in a non-auto-scanning mode.
TIB	the Bone Thermal Index.
TIC	the Cranial Thermal Index.
A_{aprt}	the area of the active aperture (square centimeters).
$p_{r.3}$	the derated peak rarefractional pressure associated with the transmit pattern giving rise to the value reported under MI (megapascals)
W_o	For TIB and TIC: time average acoustic power at the source, in milliwatts. (Also see the definitions for W_{01} and W_{01x1} that follow.) For TIS scan, $W_o = W_{o1} + W_{o1x1}$ For TIS non–scan, $W_o = W_{o1x1}$
	W_{o1}: For scanning modes and/or scanning components of combinational modes: time average acoustic power at the source, per cm, in milliwatts. This is the acoustic power emitted from the central 1–cm length, in the scan direction, of the aperture corresponding to the scanned pulses.
	W_{o1x1}: For non–scanning modes and/or non–scanning components of combinational modes: time average acoustic power at the source, per cm^2, in milliwatts. This is the acoustic power emitted from the central 1 cm^2 of the active non–scanned aperture through which the highest acoustic power is being transmitted.
$W_{.3}(z_1)$	the derated ultrasonic power at axial distance z_1 (milliwatts).
$I_{TA.3}(z_1)$	the derated spatial-peak, temporal-average intensity at axial distance z_1 (milliwatts per square centimeter).
z_1	the axial distance corresponding to the location of max[min($W_{.3}(z)$, $I_{TA.3}(z)$ x 1 cm^2)], where z = z_{bp} (centimeters).
z_{bp}	$1.69\sqrt{A_{aprt}}$ (centimeters).
z_{sp}	For MI, the axial distance at which $p_{r.3}$ is measured for TIB, the axial distance at which TIB is a maximum (i.e., $z_{sp} = z_{B.3}$) (centimeters).
$d_{eq}(z)$	the equivalent beam diameter as a function of axial distance z, and is equal to $[(4/\ )(W_o/I_{TA}(z))]^{0.5}$ where $I_{TA}(z)$ is the temporal-average intensity as a function of z (centimeters).

f_c	is the center frequency (MHz). For MI, f_c is the center frequency associated with the transmit pattern giving rise to the maximum reported value of MI. For TI, for combined modes involving transmit patterns of unequal center frequency, f_c is defined as the overall range of center frequencies of the respective transmit patterns.
Dim. of A_{aprt}	the active aperture dimensions for the azimuthal and elevational planes (centimeters).
PD	the pulse duration (microseconds) associated with the transmit pattern giving rise to the reported value of MI.
PRF	the pulse repetition frequency associated with the transmit pattern giving rise to the reported value of MI (Hz).
p_r@PII_{max}	the peak rarefactional pressure at the point where the free field, spatial-peak pulse intensity integral is a maximum (megapascals). See Section 6.2.4.1 of the Output Display Standard, entitled "Measurement Methodology for Mechanical and Thermal Indices".
d_{eq}@PII_{max}	the equivalent beam diameter at the point where the free field, spatial-peak pulse intensity integral is a maximum (centimeters). See Section 6.2.5.1 of the Output Display Standard, entitled "Measurement Methodology for Mechanical and Thermal Indices".
FL	the focal length, or azimuthal and elevational lengths, if different (centimeters).
$I_{PA.3}$@MI_{max}	the derated pulse average intensity at the point of maximum reported MI (Watts per square centimeter).

p_-	**MPa**	The Peak Rarefactional Acoustic Pressure is the maximum of the modulus of the negative instantaneous acoustic pressure expressed as a positive number.
I_{SPTA}	**mW/cm^2**	The maximum value of the temporal average derived intensity in an acoustic field. For systems in combined operating mode, the time interval over which the temporal average is taken is sufficient to include any period during which scanning may not be taking place.
System settings[a]		User selectable system settings which may include Application, SV and Focal Length.

I_p	mm	This is the distance from the transducer output face to the point of maximum pulse-pressure-squared integral (or max mean square acoustic pressure for continuous pressure for CW)
w_{pb6} (II)	mm	This is the -6dB pulse beam width in the beam axis (X) at the point of max pulse-pressure-squared integral (or max mean square acoustic pressure for continuous pressure for CW). If the beam widths in X and Y differ than less than 10%, there is no need to specify both. For scanning modes, the beam-widths shall correspond to the central scan line only.
w_{pb6} (⊥)	mm	This is the -6dB pulse beam width in the elevational axis (Y) at the point of max pulse-pressure-squared integral (or max mean square acoustic pressure for continuous pressure for CW). If the beam widths in X and Y differ than less than 10%, there is no need to specify both. For scanning modes, the beam-widths shall correspond to the central scan line only.
Prr	kHz	Pulse Repetition Rate is the rate of successive pulses or tone bursts and applies to single element non-scanning systems and automatic scanning systems.
Srr	Hz	Scan Repetition Rate is the rate of the same identical point of successive frames, sectors, or scans and applies to automatic scanning systems (modes) only.
Output beam dimensions[b]	mm	Output beam dimensions are the dimensions of the ultrasound beam (-6dB pulse beam width) in a specified direction normal to the beam alignment axis and at the transducer output face. In scanning modes, these shall refer to the center scan line only.
F_{awf}	MHz	The Arithmetic-mean Acoustic Working Frequency is the arithmetic mean of the frequencies f1 and f2 at which the amplitude of the spectrum of the acoustic signal first becomes 3dB lower than the peak amplitude.

APF[c]	**%**	Acoustic Power-up Fraction is the ratio of the peak rarefactional acoustic pressure when the system is in Power-up mode to the maximum value of the peak rarefactional acoustic pressure for any system settings of a specified mode of operation. This ratio is determined from measurements made at the position which yields the maximum pulse-pressure-squared integral (or maximum mean square acoustic pressure for CW)
AIF[d]	**%**	Acoustic Power-up Fraction is the ratio of the peak rarefactional acoustic pressure when the system is in Initialization mode to the maximum value of the peak rarefactional acoustic pressure for any system settings of a specified mode of operation. This ratio is determined from measurements made at the position which yields the maximum pulse-pressure-squared integral (or maximum mean square acoustic pressure for CW)
Maximum power[e]	**mW**	This is the Maximum Temporal Average power output. For scanning modes, this shall be the total power output of all the acoustic pulses.
I_{ob}	**mW/cm^2**	Output Beam Intensity is the temporal-average power output divided by the output beam area
Power-up mode		With the probe connected cycle power on the system. Write down the mode to which the system powers up. Usually, it is “B” mode.
Initialization mode		Write down “N/A[f] “ where it denotes “system settings do not change on new patient entry”
Acoustic output freeze		Write down “YES “ if the system is supplied with an output freeze facility.
I_{tt}	**mm**	Transducer to Transducer output face distance is the distance along the beam alignment axis between the surface containing the active face of the transducer or elements and the transducer output face (usually the lens thickness)

l_{ts}	**mm**	Transducer Standoff distance is the shortest distance between the transducer output face and the patient entry plane. The term “contact” is used to connate direct contact between the transducer output face and the patient.
Inclusive modes		Make a note of the Inclusive Modes for this particular declaration which are not being declared separately.

9.4 Specification of Components

Item	Features
Power	- AC 100-240V, 50/60Hz
Adapter	- Model: MW160 KA1641F52 (16V DC, 2.8A) (or GTM21097-5012 (12V DC, 4.17A) - Comply with UL 60601-1.
Battery	- Battery Pack: Li18S Battery cell: Li-ion rechargeable (2P-2S) - Scan: 4 hours – 1 scan in every 15sec** - Standby: 6 hours** - Charging time: Fully charging a completely discharged battery may take up to 10 hours.
Ultrasound Probe	- sector scan - 2.8MHz ultrasound frequency - B-mode scan image - scan angle : 120° - water resistance: rated at IPX1(only probe)
Transducer	- Diameter: 14mm - Resonant frequency:2.8MHz - Bandwidth: minimum 40% at 6dB - Penetration depth(normal patient): 18cm
Thermal printer	- Built in(57mm width)
Display	- 5.6〃 STN LCD - 320×240 pixels - 16 gray levels
Range	- Bladder volume range: 0 - 999ml - Accuracy*: ±15%,±15ml (0 - 999ml)
External Interface	- USB 2.0 basic

Classification of protection against electric shock	- Class Ⅰ equipment - Type BF equipment
Water resistance	- Main body: Ordinary equipment - Probe: rated at IPX1
Mode of operation	- Continuous operation.
Dimension	- 375(L)×240(W)×116(H) mm
Language	- English

*** Accuracy: According to the scanning instruction, and scanning on a Mcube Technology tissue-equivalent bladder phantom.**

**** Battery operation time: - For a new battery module fully charged**

- Tested on Mcube Technology's test conditions

10 ENVIRONMENTAL CONDITIONS

10.1 BioCon-500™

1) Operating conditions

Condition	Description
Ambient temperature range	+10 – +40℃ (+50 - +104°F)
Relative humidity	+30% – +75% non-condensing
Atmospheric pressure range	+700hPa – +1060hPa

2) Storage conditions

Condition	Description
Ambient temperature range	-10 – +60℃ (+14 - +140°F)
Relative humidity	+20% – +80% non-condensing
Atmospheric pressure range	+600hPa – +1060hPa

CAUTION:

- If you are not using this device more than a week, please disconnect battery from the device. Store the battery in accordance with the recommended conditions.

10.2 Battery Module

1) Battery Storage Conditions

Condition	Description
Ambient temperature range	-10 – +30℃ (+50 - +86°F) ≤ 1 Year -10 – +45℃ (+50 - +113°F) ≤ 3 Month -10 – +60℃ (+50 - +140°F) ≤ 1 Month
Relative humidity	+20% – +80% non-condensing
Atmospheric pressure range	+600hPa – +1060hPa

CAUTION:

- Prior to storing the battery, charge it to about 75%.

11 GLOSSARY

B-Mode	A kind of ultrasound imaging mode. Displays the brightness information corresponding to the amplitude of the signal.
Console	The main device with the LCD display.
Contextual menu	The menu displayed in the bottom of LCD based on the system state.
Session	The time a user starts to scan on Top Screen, to right before returning to the Top Screen again.
Transducer	Device that transforms one form of energy into another form of energy. Ultrasound transducer transforms electric energy into acoustic energy and vice versa. Transducer in this guide means ultrasound transducer.

12 References

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